FUNCTIONAL OUTCOME OF EXTRARTICULAR DISTAL TIBIA FRACTURES TREATED BY INTRAMEDULLARY NAILING

A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENT OF **THE TAMILNADU DR.MGRMEDICAL UNIVERSITY**, CHENNAI, TAMILNADU, FOR THE DEGREE OF **M.S. ORTHOPAEDICS** TO BE HELD IN APRIL

2016.

ENDORSEMENT BY HEAD OF THE DEPARTMENT AND PRINCIPAL OF THE INSTITUITION

THIS IS TO CERTIFY THAT THIS DISSERTATION ENTITLED '**FUNCTIONAL OUTCOME OF EXTRARTICULAR DISTAL TIBIAFRACTURES TREATED BY INTRAMEDULLARY NAILING**' IS A BONAFIDE RESEARCH WORK DONE BY **DR.SRIBALAJI PRABHU.T**, UNDER THE GUIDANCE OF **PROF. DR.THILAK.S.JEPEGNANAM**, DEPARTMENT OF ORTHOPAEDICS UNIT 3, CHRISTIAN MEDICAL COLLEGE, VELLORE.

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This is to certify that the dissertation titled **Functional Outcome of Extrarticular Distal Tibia Fractures treated by Intramedullary Nailing'** which is submitted by me in partial fulfillment of the requirement of The Tamilnadu Dr. MGR Medical University, Chennai, Tamilnadu, for the degree of M.S. orthopaedics to be held in April 2016 comprises only my original work and due acknowledgement has been made in text to all material used.

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Abstract

TITLE OF THE THESIS : FUNCTIONAL OUTCOME OF EXTRARTICULAR DISTAL TIBIA FRACTURES TREATED BY INTRAMEDULLARY NAILING

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DEGREE AND SUBJECT: MS Orthopaedics (2 yr Post diploma)

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Aim and objective:

In this study we aimed to analyse the functional outcome of extrarticular distal tibia fractures treated by intramedullary nailing. Our objective was to study the functional outcome using the American Orthopaedic Foot and Ankle Society Score and Olerud and Molander score, to assess whether these patients achieved consistent union and when they returned to work. We also assessed the correlation between the clinical and radiological scores of these patients and documented the prevalence of malunion and minor complications associated with this type of treatment.

Methods: A Retrospective observational study with prospective followup was performed on patients treated with intramedullary nailing for extrarticular distal tibia fractures during the period from January 2011 to August 2014 in Christian Medical College, Orthopaedics Unit 3.On followup, patients were assessed clinically by two examiners. Radiological parameters were recorded with anteroposterior and lateral view of the limb. Radiological and functional scores like the American Orthopaedic

Foot and Ankle Society Score and Olerud and Molander Scores were calculated using appropriate patient questionnaires.

Results: Functional and radiological scores were analysed statistically using SPSS 16.0 version statistical software. Patients with increased valgus malalignment had a delay in fracture healing compared to those with acceptable alignment. The number of patients with valgus malalignment more than acceptable criteria were 9. Results also revealed that there was no significant correlation between fibula fixation and use of Poller screws with fracture union. The average time to radiological union was 19.88 weeks. The average time taken to return to work was 29.68 weeks. 91.6% of patients had returned to their work .62.5% patients have returned to their previous jobs without any difficulty. The mean AOFAS score for both male and females was 88.23 and mean Olerud score was 81.25. The analysis revealed poor scores for females compared to males.

Conclusion: Intramedullary nailing in distal tibia fractures achieved consistent union and resulted in earlier return to work. But the rate of complications in terms of malalignment is still higher. This indicated the need for more prospective trials before concluding intramedullary nailing as a definitive indication for extrarticular distal tibia fractures.

CONTENTS

INTRODUCTION

The rapid growth of technology and urbanization has led to enormous growth of new vehicles on road. This has led to increase in road traffic injuries and deaths. Globally the number of deaths in major road traffic accidents is estimated at 1.2million deaths /year while the number injured is as high as 50 million injuries /yr. Without increased efforts to prevent these injuries the number of Road traffic deaths worldwide is projected to increase 65% between 2000 and 2020. In under developed and developing countries these deaths are expected to increase by as high as 80 %.(1)

In India, more than 1, 00,000 lives are lost due to road traffic accidents every year (WHO global safety report 2011)(2). According to WHO Report in 2002 road traffic injuries were ranked as the ninth cause of death in all and ranked as fourth cause of death in 2008.In India it is ranked as 6^{th} leading cause of death(2). A 4.4 fold increase has been detected in the number of road traffic accidents between the years 1970- 2011. Subsequently the number of deaths has increased by 9.8 folds and the number of injuries by 7.3 folds. To note is that one third of fatalities in India involve the pedestrians and two wheelers who are called as the 'vulnerable road users'(1). Under developed and developing countries account for 91.8% of DALY's lost to road traffic injuries worldwide.

The injury due to these accidents commonly involve the long bones especially tibia due to its subcutaneous location. On the basis of location, distal tibia fractures are second in incidence next to tibia diaphyseal fractures(3). The distal tibia due to its subcutaneous blood supply and tenuous blood supply pose a challenge to treating surgeons in terms of choosing an appropriate implant to achieve adequate union and return to early preinjury levels.

It was in 1969(4) the treatment of distal tibia fractures got revolutionized by the study done by Reudi and Allgower where 74% of patients after surgery were pain free with good functional outcome at 4 years follow-up. Therefore in 1970’s and 80’s widespread use of internal fixation for distal tibia fractures became popular. However this was also accompanied by a high rate of major complications like malunions 42%, superficial infections 20%, non-union in 18% and osteomyelitis in 17%. These high rates of complications emphasized the importance in handling soft tissues during fracture management. But all these fractures in Reudi and Allgowers series were low energy injuries. They published another series in 1979(5) which consisted of high energy injuries and found that overall results were not good. This led to methods which caused less soft tissue damage and yielded better results. The new techniques used were Intra Medullary nailing (IM nailing), hybrid fixators and biological minimally invasive plate osteosynthesis (MIPO).

AIM AND OBJECTIVES

AIM:

TO ANALYSE THE FUNCTIONAL OUTCOME OF PATIENTS WITH EXTRARTICULAR DISTAL TIBIA FRACTURES TREATED BY INTRAMEDULLARY NAILING.

OBJECTIVES:

1. To study the functional outcome of patients with extrarticular distal tibia fractures treated by intramedullary interlocking nailing using American Orthopaedic Foot and Ankle Society Score (radiological) and Olerud and Molander scores (clinical).

2. To assess whether the patients treated by this modality achieved consistent union and when they returned to work.

3. To assess correlation between the clinical and radiological scores of these patients.

4. To document major complications (Prevalence of malunion) and minor complications associated with this treatment modality.

HISTORICAL REVIEW

EVOLUTION OF INTRAMEDULLARY NAILS:

In the 16th century the Aztec physicians in Mexico(6) placed wooden sticks into the medullary canal of patients to treat long bone non-union. The introduction of ivory pegs into the medullary canal was done by Stimson in mid-1800 to treat non-union(6). It was in 1917, Hoglund from United States, who introduced autogenous bone as an intramedullary implant(6). Alternative methods of treatment of proximal femur fractures were done by Rush and Rush in 1930(6),where they used Steinmann pins in the intramedullary canal as stabilizing devices. The principle of closed nailing and stable fixation were introduced by Gerard Kuntschner, in 1940, who developed ‘V’ nail and clover- leaf shape nails(7). The special triflanged nails for treating fractures of femur and tibia were invented by Lottes,in 1950(7). Modification of the straight Kuntschners nail to a nail with proximal bend was done by Herzog, in mid 1950(7) to accommodate the eccentric proximal portal. Grosse, Kempf, Klemm and Schellman, in 1970(6), developed nails with interlocking nails which expanded the indications for nailing to include more proximal fractures, distal fractures and unstable fractures.

AO PRINCIPLES OF FRACTURE MANAGEMENT: EVOLUTION AND EVALUATION:

The Swiss surgeons of the 'AO' group realized that immobilization of the limb for treatment of fractures resulted in atrophy of soft tissues, articular cartilage damage, osteoporosis, causalgic pain and severe joint stiffness. To overcome these complications they introduced the concept of 'functional after treatment'. This concept was to provide stable fixation of fracture achieved surgically which eliminated pain, so early and full mobilization of extremity was possible(8). The surgical treatment for fractures emphasized that reduction has to be anatomic, fixation to be sufficiently rigid, stable, lasting to allow functional use without the risks of hardware failure. Soft tissue handling was also given equal importance. The instrumentation expanded to include not only plates and screws but also nails. Extramedullary implants always participate in load transmission and may cause stress shielding. Since refractures following plate removal were thought to be due to stress shielding, many researchers were working on plate stiffness. However the AO research institute in Davos, Switzerland, began to investigate biological effects and particularly the effect of the plates on bone circulation. The investigators were able to show that plates interfered significantly with the blood supply to the underlying bone and caused the underlying cortex to become avascular. This discovery headed towards a major shift within the AO, with the modification of the techniques and principles of internal fixation. The emphasis shifted from mechanics involved in fixation towards preservation of local biology. This resulted in designing new less invasive implants to match these changes. The invention of locked IM nailing, which was based on the development of the Kuntschner ‘Detensor’ nail and described by Kempf and Klemm et al, was a major breakthrough. Closed nailing preserved the soft tissue attachment of fracture fragments, which in turn preserved their blood supply. Fracture union after closed nailing was rapid with abundant callus formation(8).

INTRAMEDULLARY NAILING IN DISTAL TIBIA FRACTURES: AN OVERVIEW:

Distal tibial metaphyseal fractures are the fractures which extend within approximately 4cm from the tibial plafond(9). Extrarticular fractures are those with no extension of fracture line into the tibial plafond(10).

The anatomy of the tibia is peculiar, where in an axial cross section on examining from the diaphysis to metaphysis, the shape of tibia shows a transition from that of a triangular configuration to a more circular shape(11). The central medullary canal of the tibia has acquired the shape of a hour-glass where the mid one third of the shaft is narrow and the proximal and distal third appear wider(12).Thus while performing an intramedullary nailing the largest possible nail diameter can provide a tight endosteal fit only at the middle third of the shaft(11,12).

The extramedullary blood supply of tibia, especially of the mid one third and distal one third is of particular importance in fracture healing. The anterior and posterior tibial arteries supplies the exterior 1/10th to 1/3 of the tibial cortex whereas the interosseous blood vessels supply the remaining inner 1/3 cortex(13).

Beyond the vessels the relationship of the great saphenous vein and saphenous nerve is important particularly when considering plating of tibia fractures. The vein and the nerve crosses each other at the posterior cortex of tibia at an average 10cm from the tip of medial malleolus. Using cadaver model, these structures were found at greatest risk during medial plating of tibia at 2 cm to 4.6 cm from the tip of medial malleolus(14).

The relationship of fibula is posterolateral to the tibia and articulates with it at the superior and inferior tibiofibular joints. The distal tibiofibular joint along with syndesmotic ligaments of the ankle are important in the fact that they help in maintaining the alignment of distal tibia during fracture healing (15).

INTRAMEDULLARY NAILING:

Intramedullary nails provide a stable fixation with advantage of minimal soft tissue dissection. But the indications for IM nailing in proximal or distal metaphysis have not been clearly defined. In more distal metaphyseal fracture of tibia, IM nailing is unstable as a result of decreased contact between the bone and the nail. When the contact between the nail and bony cortex is poor distal to the fracture site, a higher proportion of mechanical load will be taken over by the nail and will be transmitted to the distal screws. This results in inferior load sharing ability of the screws that ultimately lead to screw failure(16). This leads to the increased rate of malunion and non-union reported by several authors in their studies that compared IM nailing with plating. Multiple techniques exist to add stability to these constructs like fibular fixation, blocking or Poller screws, multiplane distal locking screws.

Fibula fixation in distal metaphyseal tibia fractures adds stability to the ankle joint and aid in tibial fracture reduction and union. Usually if the length of the tibia is normal, its axis and rotation are not achieved by standard methods of reduction. The fibula is plated first using a flexible tubular plate to provide stability laterally while permitting tibial length and alignment to be corrected(17). But studies done by Vallier in 2008(18)demonstrated high rate of non-union in fractures treated with fibula fixation 14% vs 2.6% where fibula was not fixed. Valliers study in 2011(19) also revealed similar results. But in IM nailing, fibular fixation was recommended especially in extensively communited fractures in which rotational and saggital alignment are difficult to maintain with IM nailing alone(15). Another study by Kumar et al (20) has confirmed that fibular fixation in the setting of IM nailing reduces malunion and angular displacement.

Another method of improving alignment of distal tibial fractures along with providing stability is the addition of blocking screws or Poller screws. These screws are inserted in sagittal or coronal plane adjacent to the concave side of the deformity to effectively decrease the diameter of the medullary canal distally(21). Angle stable locking screws when compared to conventional screws have a larger diameter near the head of the screw(22). These angle stable screws have a sleeve that expand to fit the interlock of the nail, creating an angle stable interface between the nail and the cortical screw. Biomechanical studies have demonstrated improved structural stability of the construct with the use of angle stable screws(22).

Screw configuration, placement of screws in multiple plane have not proven superiority of one over the other in biomechanical studies. Biomechanical studies demonstrated no significant difference in angulation when screws were placed perpendicular in orientation or parallel to one another(23)(24).

In addition to screw configuration the choice of implant also plays an important role in achieving adequate fixation. The length of the nail must closely match the length of the tibia to allow two distal locking screws. Selection of appropriate nail length can be done preoperatively by measuring the medial joint line to tip of medial malleolus in the uninjured limb(25).

Another frequently reported complication after IM nailing apart from malalignment is the residual knee pain(19). The cause of knee pain appears to be related to the injury to the soft tissues during surgery particularly to the patellar tendon and retropatellar fat pad. A Study done by Weil et al (26) in which patients underwent IM nailing with a para patellar approach with meticulous dissection of retropatellar fat pad demonstrated relatively low incidence of knee pain 19% vs 50% which was reported by Robinson et al(27) and Bedi et al(28) using Patellar tendon splitting approach.

Despite all above, IM nailing is particularly advantageous in several situations, especially in older patients with thin skin, those with compromised soft tissue, diabetic patients in whom healing is a concern and the presence of fracture blisters in the skin.

In addition fractures without distal extension that allow placement of at least two distal interlocking screws in distal fragment are particularly suitable for nailing(9).

The difficulties in the treatment of fractures of shaft of tibia especially distal one third fractures include(29)

1) High incidence of open fractures because the tibia lies just beneath the skin.

2) High chances of redisplacement of fragments when swelling subsides especially in oblique and spiral fractures since very less muscle cover.

3) Serious disability if there is a rotational or alignment mismatch because the knee and ankle joints normally move in the same physical axis.

4) Obvious disfigurement of the leg will be evident if fragment opposition is not perfect since tibia lies subcutaneously.

5) High chances of delayed union since there is poor supply to the distal fragment.

6) Increased chances of non-union if delayed union is not recognized immobilization is not suitably prolonged.

7) A tendency for recurrent edema of the foot and ankle.

8) A tendency of rigid clawing of toes if early exercise is not practiced.

In literature, there are no proper clinical indications for intramedullary nailing for distal extra articular tibia fractures. The definitive indication for IM nailing in distal metaphyseal extrarticular tibia fractures have not been proposed because of the major complication of increased rate of malalignment.

The reasons explained for not considering IM nails as standard care of treatment in distal tibia fractures includes

1. Distal tibial metaphysis does not offer a snug fit for IM nails.
2. Placing the nail in centre in proximal and distal fragments is of utmost importance to get an acceptable alignment.
3. There is increased stress of the distal locking bolts to maintain fracture reduction and after surgery because of minimal cortical contact in the metaphyseal region.

The decision to fix fibula and also the use of number of distal locking bolts and their orientation also influences the maintenance of fracture reduction and prevention of subsequent deformity.

The choice of intramedullary nailing in extrarticular distal tibia fractures can be justified if the vasculature of the tibia is clearly understood. It brings out the potential disadvantages in using plates which may hinder the blood supply to the cortical bone and the callus leading to delayed union or non-union.

VASCULAR ANATOMY OF THE HUMAN TIBIA:

There needs to be a rich blood supply for the formation of fracture callus. There exists three system of vessels in all tubular bones(30).

1. Nutrient vessels
2. Metaphyseal and epiphyseal vessels
3. Periosteal vessels

Nutrient artery:

The course of nutrient artery of human tibia is described in detail by Crock(31). It arises from the anterior aspect of the posterior tibial artery, very close to the origin of the posterior tibial artery from the popliteal artery. The vessel enters the bone posteriorly in a descending direction, slightly closer to the proximal than the distal end of the bone. The nutrient artery then penetrates the tibialis posterior muscle close to its origin from the bone. It enters a groove on the posterior surface of the tibia leading distally to a very oblique nutrient canal which in humans may traverse the cortex for a distance of 5.5cm. In the long sub periosteal groove and osseous canal, the nutrient artery is vulnerable to injury by even a slight displacement of fracture.

The nutrient artery lies close to the lateral side of the bone but as it reaches the medullary canal it passes centrally to divide into ascending and descending branches.

Ascending branch:

The ascending branch of the nutrient artery of tibia after entering the canal initially passes downwards and medially and then turns abruptly towards forming a single or double loop. The artery divides into 3 or more ascending branches which pass upwards towards metaphysis breaks into innumerable fine branches which provide blood for most of the metaphysical side of growth cartilage.

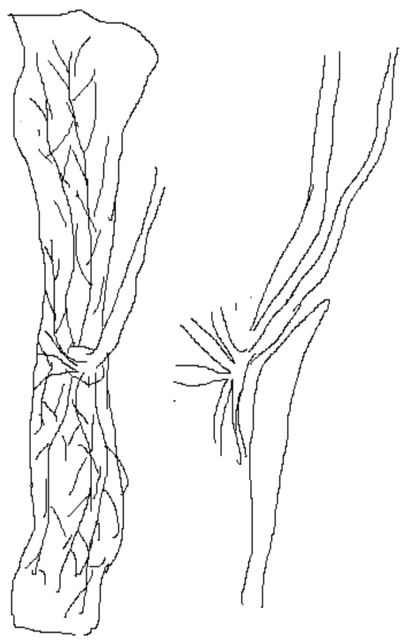

Figure 1. Course of nutrient artery in tibia

Descending branch:

Lies close to the posterior cortex and as it reaches lower metaphysis it gives small branches which enter the cortex.

Periosteal arteries:

The Periosteal layer is represented by several arteries which run from above downwards without any appreciable decrease in calibre. They arise from the anterior tibial artery. As they pass close to the surface of the bone they give of many branches, mostly at right angles to the main trunk.

A longitudinal view of the cortex shows that the vessels are parallel to the surface of the bone and unite with the vessels lying below them through communicating branches, which give a lattice appearance.

The number and calibre of the periosteal vessels which pierce the cortex are small in the centre of the shaft, progressively increasing towards both metaphysic and reaching maximum as the distal part of the epiphysis is reached.

Studies with vascular perfusion method and particularly with fluorescent microscopy have shown that periosteal vessels profusely penetrate across the cortex at the place where the interosseous membrane is attached. This may explain why most fractures of the distal third of the shaft begin to unite from the area of attachment of the interroseous membrane.

SUMMARY OF THE VASCULATURE OF THE TIBIA:

The tibia has an extremely rich vascular supply at its both ends extending till the region of the diaphysis. However the increase in density is inversely proportional to the reduction of bone thickness. The disproportion between the small areas occupied by the vascular marrow and the large compact mass of bone substance is most remarkably distinctive. These results in decreasing vascularity. This has an influence in decreasing the rate of bone healing. It has also been discussed that only along the line of attachment of the interrosseous membrane, at the back of the shaft of distal tibia there is sufficient vasculature to build an effective but slow callus.

The contribution of endosteal callus in the healing of fractures is complementing that of the periosteal callus and in cases when acting alone the rate of union is delayed(30).

In clinical fractures of tibia, union of fractures relates very importantly to the site of the fracture. The upper epiphyseal-metaphyseal region is the area which produces earliest union when fractured and the distal end of shaft is most likely to be affected by delay or lack of union.

PARTICIPATION OF 3 SYSTEMS OF VESSELS IN CALLUS FORMATION:

On studying the three main sources of blood to the bone in callus formation, it was found that the periosteal vessels were the only the source of nourishment to the callus. The more intense vascular reaction of the periosteum helps in a quicker formation of the periosteal callus. The suppression of intramedullary blood flow, by a law of compensation increases the vascularity of periosteum.

The union is caused by periosteal callus and takes a slightly shorter time to be accomplished. In experiments in which periosteal blood flow was suppressed and endosteal circulation remained intact, endosteal callus formed but the union was delayed. This correlated with the findings of Tonna and Cronkite’s study(32) of the cellular response to fracture. They noted that maximum proliferation was seen in periosteum 32 hrs after fracture. The contribution of the peripheral vessels to the organization of the callus is much earlier and much greater than that of endosteal vessels. Moreover the suppression or severe decrease of the bone marrow blood flow seems to activate the periosteal circulation, thus paradoxically, the rate of consolidation is higher than it otherwise would be.

Trueta(30), concluded that the tibia is an ideal example of the rate of bone healing in relation to the vascular supply. A fracture of tubular bone cannot be produced without rupture of the nutrient artery and also of disturbance to the peripheral vessels. The suppression of the peripheral callus by the introduction of plates and screws cause a severe interference with the normal process of bone union.

ROLE OF PERIOSTEAL BLOOD SUPPLY IN HEALING OF FRACTURES OF TIBIA:

The periosteal vessels supply the outer 1/3rd of the bony cortex. The periosteal vessels are derived from the main vessel of the limb, the anterior tibial artery and run transversely to the long axis of the bone. This becomes very important when there is a long bone fracture since the nutrient vessels are completely disrupted. Since they run longitudinally, the distal fragment is rendered avascular upto the point where the metaphyseal vessels enter the bone. Since the periosteal vessels run transversely to the long axis of the bone, the blood supply to the periosteum is maintained on both the sides of the fracture line. The viable periosteum on the proximal and distal fragments can now hypertrophy and rapidly seal the gap.

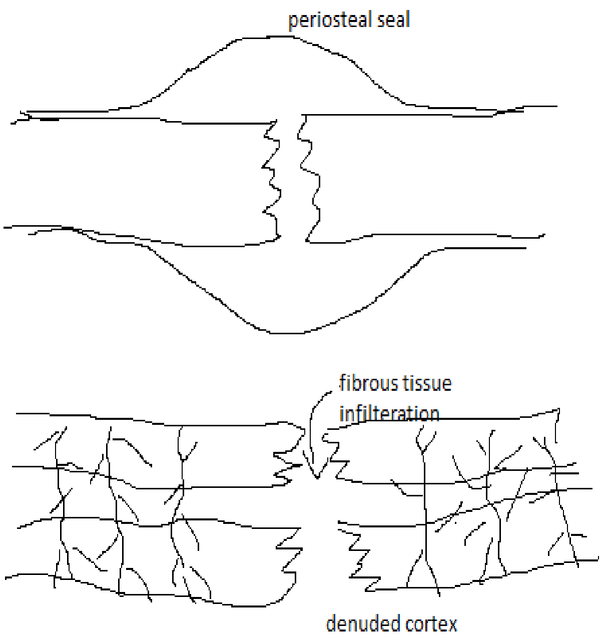

Figure 2. Function of Periosteal seal

The importance of the periosteal seal also lies in preventing infiltration of fibrous tissue. The periosteal vessels are also vitally important in re-establishing the endosteal circulation in the distal fragment(33).

In animal experiments when the periosteum was destroyed, the circulation in the distal fragment was slowly re-established and the distal endosteal callus formed at some distance from the fracture site. But if the periosteal vessels are left intact they help in establishing the endosteal circulation upto the fracture site. When this occurs, the endosteal callus in the distal fragment form at the fracture site. This suggest the important role played by the periosteum and its vessels in preventing a fibrous union and accelerating fracture union.

It has been commonly stated that fractures of lower one third of the tibia are slow to unite because the blood supply of this portion of the bone is poor. However Macnab and De Haas (33) stated that the vascular supply of the lower one third of the tibia was found to be no less than elsewhere in the shaft. In fractures of the tibia distal to the entrance of the nutrient artery, a greater portion of the shaft of the tibia is rendered avascular, as opposed to the fracture of the lower third, where the shaft lies near to the distal metaphyseal vessels and hence distal shaft revascularization can be readily accompolished.

The lower third of the tibia is not surrounded by muscles and severe Displacement of fragments occurs with greater energy of injury. Moreover the periosteum is likely to be stripped by such displacements. It is therefore the greater incidence of periosteal damage found in the fractures of the distal third of tibia that delays the healing.

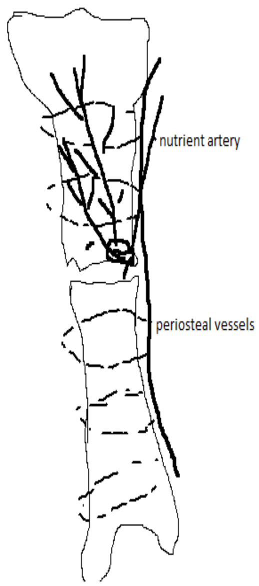

Figure 3. Intact periosteal blood supply in fractured bone with loss of endosteal supply

So the longitudinal endosteal supply is interrupted by fractures while the transverse blood supply conveyed by the periosteum sustains viability on both the sides of the fracture site. The intact periosteum seals the fracture gap and the periosteal vessels revascularize the distal fragment. Therefore the integrity of the periosteum is of vital importance in determining the healing of fractured tibia.

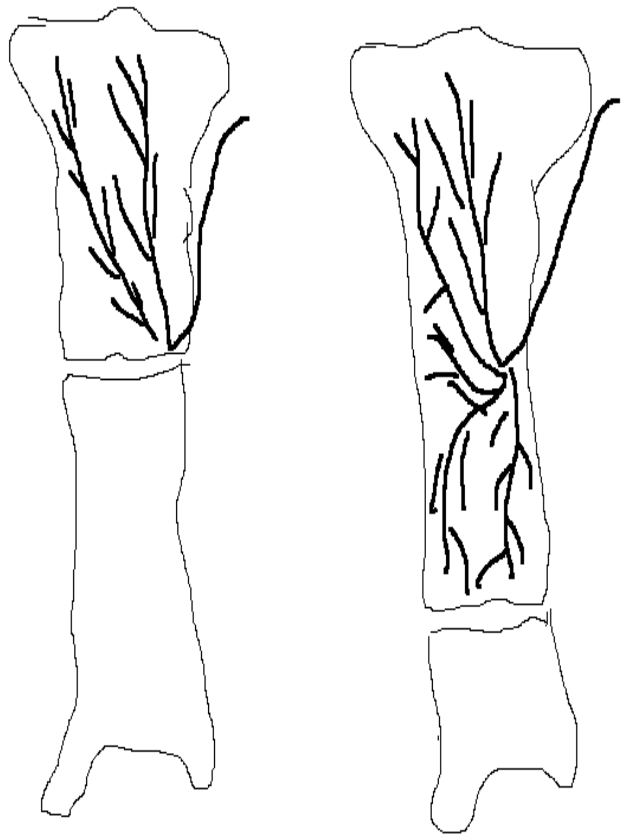

Figure 4. Far greater portion of bone is rendered avascular when fracture occurs in upper third

Distal metaphyseal tibia fractures are not so common. In a series of analysis of 5953 fractures, Court-Brown and Ceaser(3) reported 0.7% of fractures only of the distal tibia. Totally they accounted for 13% of all tibia fractures. Fan et al(34) also evaluated fractures of distal tibia and found it to be only 10% of all tibia fractures.

Nailing of distal tibia fractures involves technical difficulties which differ from a simple or communited diaphyseal fracture of tibia. In diaphyseal fractures nailing automatically aligns the fracture and locking is also straight forward with goodstability with preservation of soft tissue and hematoma around fracture site. But the situation in distal tibia fractures are completely different. Here nailing does not automatically align the fracture. The fracture being subisthmically situated with enlarged metaphyseal region, there is considerable amount of nail mobility which makes nailing difficult and unstable(35).

According to Gorczyca et al(36),for rigid and static nailing in distal tibia fracture there should be atleast 3-4cm of bone beyond the fracture. Hence he suggested sawing of the distal end of nail to provide most distal locking but currently this is not required as nails with more distal locking screws are readily available.

Gorczyca and Egol(15,36) also inferred that there is also need for distal screw fixation in more than one plane to obtain better control of frontal, sagittal as well as horizontal movements by distributing the stress. This multiplanar fixation provides better stability of fixation mainly in the axial compression, which helps in postoperative rehabilitation and early mobilization.

Risk factors for defects in reduction as reported in the literature includes poor surgical technique with a poor entry point or improper positioning of the guide (which must be centered on the profile and slightly lateral on the front) apart from the metaphyseal enlargement and communition of fracture site.

The level of expertise shown by the operating surgeons does not significantly explain the malalignment or axial deviation observed. It has been confirmed by Obremsky and Medina(37).The fibula plays a major role in stabilizing the ankle during walking. The delay in union of tibia in the presence of an intact fibula was about 22% as reported by Teitz et al(38). Some authors Delee , Heckman (39) did either a partial fibulectomy or fixation of the fibula.

The mechanisms of injury resulting in distal metaphyseal tibial fractures usually are of high energy injury and they not only create complicated communited fractures but also extend the injury to soft tissues. So open reduction and internal fixation of these fractures were associated with wound dehiscence, skin sloughing, malunion, infection, implant failure(40). Further in patients with soft tissue dehiscence and infection leading to osteomyelitis 16.6% had amputation(41).

RETROSPECTIVE STUDIES:

Mosheiff et al(42) in 1999, did a retrospective study involving 52 patients who sustained distal tibia fractures. He included fractures with or without articular involvement but predominantly extrarticular. All patients were treated with unreamed tibial nailing. The advantages stated were, the structure of the nail enabled 3 interlocking screws distally, the narrow diameter of the nail enabled percutaneous insertion of additional interfragmentary screws, apart from the advantage of causing no harm to the endosteal blood supply. Patients were followed up for average 18 months. 50 of 52 fractures united well. The mean time taken to union was 15.3 weeks. 43% of cases needed additional procedures like dynamisation and 40% needed additional surgery like bone grafting. There was no shortening varus/valgus deformity. This is one notable study was unreamed tibial nails showed excellent results.

In 2000, Dogra et al(43) published results of 15 patients with distal tibial fractures treated with reamed IM nails which were shortened by 1 cm just distal to the lower most locking screw to accommodate 2 locking screws distal to the fracture site.Clinical assessment included rotational malalignment, time to full weight bearing and limb length discrepancy. The mean followup was 4.7 yrs. Patients started full weight bearing at an average 5.5 months and mean time to return to work was 5 months. The mean time to radiological union was 20 weeks. All patients had good ankle and knee range of motion. 2 patients needed nail dynamisation and 1 patient needed bone grafting. 3 patients healed with malalignment. This was the first study in literature with shortened tibial nail. The authors at the end of the study strongly recommended redesign of tibial nails which would help in fixing distal tibial fractures.

Gorczyca(36) did a biomechanical study in 2002 on consequences of treating distal tibia fractures with modified tibial nails by cutting their distal tip. Main outcome measured was stiffness for each type of loading to compare stability of modified nail construct to that of standard nail. They found that 4cm distal tibial fragments stabilised with modified nails have comparable stiffness in compression and torsional loading to standard tibial nails but on moderate compression bending, the nail failed in three ways. Movement of nail in cancellous bone, movement of nail in coronal plane on interlocking screws, movement of interlocking screws through the bone. Addition of second interlocking screw increased the resistance to movement of nail over the screws. He recommended weight bearing restrictions after surgery owing to above complications to prevent malalignment.

18 patients were reviewed by Megas et al (44)in 2003. The mean followup was 38 months. All fractures united at an average of 18 months. All patients returned to normal daily activities. No shortening was noted. He recommended all fibular fractures located upto 10cm proximally from the lateral malleolus should be fixed. This facilitated tibial fracture reduction, limb length maintenance and its axis during nailing.

In 2005,Nork et al(45), analysed 36 tibial fractures retrospectively which were treated with reamed intramedullary nailing with use of either 2 or 3 distal locking screws.33 fractures united with acceptable radiographic alignment. 30 fractures united without any additional procedures at an average of 23.5 weeks. Fibular plate was used as primary reduction aid in 53% patients to achieve alignment, rotation and to obtain length. Difficulty in reduction of distal tibial fragment was not addressed using blocking screws instead alternative reduction methods were used like fibula fixation with plate prior to nailing, temporary reduction of tibia with unicortical plate in patients with open injury, reduction with a percutaneous clamp and placement of femoral distractor.

Prospective studies by Cheng-Yu fan and his colleagues in 2005(34), revealed that tibial interlocking nailing was a reliable and safe method for managing metaphyseal fractures of distal tibia. 20 cases were enrolled and all fractures united with mean union time of 17.2 weeks. All patients returned to their former employment with full weight bearing. No implant failure, shortening or malunion was reported.

Janssen Jaspers paper in 2007(46) analysed retrospectively 24 patients of extrarticular distal tibia fractures treated by IM nailing and ORIF with plating. The mean time to radiographic union was 21 weeks in IM nailing group vs 19 weeks in plating group. The time to full weight bearing was 3.3 months in IM nailing group vs 3.8 months in plating group. Both groups returned to work after a mean time of 6 months. The significant results was the increased rate of varus/valgus malalignment in IM nailing group (16.7%) vs none in the plated group. The incidence of anterior knee pain was also high in the IM nailing group. They concluded that in distal third tibia fractures IM nailing alone cannot control the alignment in all directions and

hence plating of fibula may be necessary to obtain less malalignment as suggested by some authors(44). Vander schoot et al in 1996(47) analysed patients with tibia fractures who had residual malalignment and found an increased incidence of osteoarthritis in the
affected side knee and ankle.

Another notable article by Ehlinger et al, in 2010(35), where 51 fractures of distal tibia were studied with a working hypothesis to rectify problems encountered with nailing alone of distal leg fractures. The bone union rate was 97.6% at a mean 15-17 weeks. The mean Olerud functional score was 83.5 points at 12 months. 14 cases of axial deviations were observed with more than 5 deg .This comprised the malunion group which was clearly higher in rate than reported in early literature. Mean Olerud score for malunion group was 72.9. 2 cases had deep infections. The lack of fibular plating was the only significant factor found in initial axis deviation, as well as in maintaining reduction over time. They recommended fixation of the fibula first and to be precise and rigorous in technique of nailing to decrease malunion rates.

RANDOMIZED PROSPECTIVE STUDIES COMPARING PLATING AND NAILING:

A landmark prospective study by Vallier et al(19) in 2011 revealed some interesting data on both modalities of treatment for distal third tibia fractures. This was a prospective randomised controlled study with level 1 evidence where they analysed 104 fractures (56 in each group).

The results were as follows:

	IM nailing	Plating
Primary angular malalignment	23%	8.3%
Non-union rate	7.1%	4.2%

The most common deformity was valgus malalignment. The trend towards non-union after fibula fixation was 12% when fibula was fixed and 4.1% when fibula was not fixed. The rate of infection was 83% after open fractures. The primary union rate after closed fractures was 100% in both the groups. The authors concluded that high primary union rates were achieved after surgical treatment with both plates and nails. IM nailing had more malalignment than plating. Open fracture was associated with more rates of non-union, infection and malunion. Fibula fixation during surgery facilitated anatomic reduction of tibia but observed more tibial non-union with distal fibula fixation.

Heather Valliers earlier study in 2008(18) also revealed 5 out of 6 non-unions occurring in open fractures and with fibula fixation along with increased risk for cigarette smokers.

A Prospective RCT by Gun et al (48) in 2005 analysed 64 patients 34 in IM nailing group and 30 in plating group. Results showed that time to union was similar in both groups, nearly 18 wks in IM nailing and 20 wks in plating. The one advantage identified were patients in IM nailing group have statistically higher range of ankle dorsiflexion. Duration of surgery was short in the IM nailing group (17 mins shorter than plating) with, lower incidence of wound infections (Plating 23% Vs IM nailing 3%). The Soft tissue complications occurred despite postponing the surgery upto 14 days to allow the soft tissue injury to resolve in the plating group. They concluded by recommending IM nailing in fractures of distal tibia associated with soft-tissue injury more than Tscherne Gotzen grade C2. Both treatments yielded same results in other classes.

Guo et al(49) in 2010 published his results on a RCT comparing IM nailing and MIPO. This was the 1ST Study to compare these two methods of treatment. 85 patients with 44 in IM nailing group and 41 in MIPO group. The time to union was similar in both the groups IM nailing 17.7 wks and MIPO 17.6 wks. However the IM nailing group had better function, alignment and AOFAS scores even though the difference was not significant statistically. Wound complications were higher in MIPO (14.6 %) vs IM Nailing (6.8%). This occurred even after considerable delay of upto10 days for certain cases to be operated to reduce swelling and bruise. IM nailing showed a clear advantage in earlier operation, less operative time, better functional scores and ease of removal of implant. Hence they recommended IM nailing as the preferred treatment in treating distal metaphyseal fractures of tibia in OTA type 43 A. Open Gustilo types 2 and 3 were excluded from this study.

A Randomized pilot trial was done by Mauffrey et al,(50) in 2012 with 24 patients, 12 in the IM nailing group and 12 in the Plating group which showed an advantage in using IM nailing. Poller screws were used in 4 cases of IMN group. Fibula was not fixed in any of the plating group. There were 3 delayed unions in the plating group and 6 superficial wound infections. More of plating group patients complained of symptomatic hardware and had their implant removed. Primary outcome assessment at 6 months post op favoured nailing in terms of fracture union, wound complications, but the advantage began to diminish at 12 months assessment suggesting need for larger trials to arrive at a conclusion.

METAANALYSIS ON DISTAL TIBIA FRACTURES:

A systematic review was done by Boris Zelle et al (51), with 485 in the IM nailing group, 115 in the Plating group. No prospective RCTs were included. 15 retrospective case series were included including 1 retrospective comparative study. Overall point estimates suggested that malalignment and non-union rates were similar in both groups. The IM nailing group had a non-union rate of 5.5%, malunion rate of 16.2%, infection 4.3% whereas the plating group had a non-union rate of 5.2%, malunion rate of 13% and infection 2.6%. The 521 fractures treated non-operatively showed a malunion rate of 15% and non-union rate of 1.3 %. Though the rate of non-union and malunion were low in the non-operative treatment group the number of open fractures was significantly higher in nailing group and no open fractures were included in nonoperative treatment group.

A large meta-analysis of articles was done by Tao Yu et al(52) which was In 2012. He analysed articles from 1975 Jan to 2011 Dec. 22 studies with 880 fractures including 15 groups of IM nailing and 15 groups of plating were analysed. He excluded mixed intraarticular and extrarticular fractures. Results showed shorter healing time with IM nailing though malunion rate was significantly higher than the plating group. The average operating time was longer with the nailing group but was not statistically significant .The re-operation rate was higher in nailing group but no statistical difference was found when comparing rates of non-union, infection, rotation, shortening and delayed union. Though they concluded plating group superior overall to some extent than nailing, the functional outcome was similar between two treatment groups.

Kwok et al (53) studied IM nailing and plating and included 8 studies, 4 prospective and 4 retrospective, including 455 fractures. They found no significant difference between plating and nailing regarding bone union and complication rate like wound infections. Plating was associated with a lower risk of malunion when compared with IM nailing. An important observation made was that innon-randomized trials bone union complications may have been because of selection bias of fractures with most severe soft tissue damage and communition to be treated with a nail, therefore over estimating the occurrence of non-union as complication in nailing groups.

Most significant results favouring IMN were obtained in the article published by Xing –He Hue(54). He analysed 14 studies, including 842 patients. IM nailing had higher pain score and functional score than that of plating. The malunion rate of IM nailing was considerably higher than plating but when prospective trial were included there was a trend towards decreased rate of malunion in IM nailing group. Results also demonstrated excellence of IM nailing over plating in infection rate. Another important data result was time to union with IM nailing was less (17.7 to 22.6 wks in IM nailing group Vs 17.6 to 27.8 wks in plating group) than plating.

Analysis of both RCT s and observational studies done to compare nailing with plating for distal tibia fractures was published by Mao et al(55) recently in 2015. He found that only 5 RCTs with 420 fractures were able to provide level 1 evidence, so the total number of RCTs was very small. Results showed IM nailing was associated with significantly more malunion and higher incidence of knee pain in retrospective subgroup but not in RCTs and lower rate of delayed wound healing and superficial infection both in RCT and retrospective groups relative to plating .Reports of knee pain averaged at 32.6 % in IM nailing vs 8.5% in plating. Rate of instrumentation removal was 16% for IM nailing vs 20.1% for plating. Rate of secondary procedures were 24.1 % in IM nailing vs 30% in Plating.

Most debatable complications were delayed union and malunion. There was no significant difference with delayed union but malunion rate showed a significant difference favouring the plating group.

Some tips for IM nailing recommended were:

1. The distal fragment should have enough bone volume to receive and hold atleast two screws.
2. Surgeons should use straight guide wire and master the techniques of blocking screws and multiple plane locking screws.
3. Suitable nail length and careful treatment of soft tissue for minimising incidence of knee pain.
4. IM nailing may be suitable for particular populations such as patients for whom there is a concern about wound healing like older patients with thin skin and diabetic patients.

PREVENTION OF MALALIGNMENT-ROLE OF POLLER SCREWS:

The frequent complication of intramedullary nailing in distal third tibia fractures are malalignment following fixation. This is due to the short distal fragments which gets rotationally malaligned if the guide wire is not placed centre-centre in ap/lateral view. The malalignment may result from incorrect entry point also. The other factor involved is the large diameter of the metaphyseal area with smaller diameter nails. This can be avoided by using of “Poller screws” which serves as an additional stabilizing technique and reduction tool in nailing of tibia.

In 1983, it was Donald and Seligson who first referred to “Blocking screws” in their article for fractures predisposed to bending. But in 1999 Krettek(56) describedthe clinical use of blocking screws as a reduction tool in preventing frontal and sagittal plane deformities in distal third tibia and femur fractures. He used the term “Poller screws”.

Poller screws functionally reduce the diameter of the medullary cavity in the metaphyseal region, prevent the transverse nail translation and increase the stiffness and strength of bone-nail construct.

In his study (21)Krettek he demonstrated that in tibial nails, mediolaterally directed locking screws provide stability in sagittal plane only and they are less stable in frontal plane movement. Hence sagittaly directed blocking screws can increase the primary stability significantly in addition to frontally directed interlocking screws.In his observation(21) fractures stabilized with 2 mediolateral and 1 anteroposterior screw demonstrated 57% less fracture stiffness compared to fractures stabilized with additional blocking screws. Though smaller in size the primary stability achieved by blocking screws is significantly large which helps in preventing malalignment.

Recently Chan et al(57) did a biomechanical analysis to study the effect of number and position of distal interlocking screws in IMN in distal tibia fractures. They studied the effect of three screw constructs 1.Two distal locking 2. Three distal locking 3. Two distal locking and 1 Poller screw.

They found out even after 12 cycles of axial loading the saw bone model with upto300% body weight none of the three showed evidence of progressive deformation but the 3 distal locking construct offered the highest mechanical stability. This was in contrast to the finding of Krettek et al that two blocking screws placed medial and lateral to an 8mm dia nail increased stiffness of the construct by 57%. This was explained by the smaller diameter 8mm nail and 3.5mm screw used by Krettek vs 10mm nail and 5.0mm screw used in this study.

RATIONALE BEHIND FIXATION OF FIBULA FRACTURES:

The role of fibula fracture fixation in case of distal extrarticular tibia and fibula fractures have been studied both in clinical situations and lab conditions. It has been demonstrated that fibula plating improves fracture alignment, ability to resist the movements across the defect, prevents deformity post-surgery and prevents loss of reduction.

Comparing the different loading situations in cadaveric models in fractures with intact fibula and fractured fibula was done by Eric Strauss et al(58). They observed plating the fibula not only increased the construct stiffness in case of

Intramedullary nailing but also served as primary reduction aid in obtaining appropriate length, alignment and rotation of the distal tibial fracture fragment.

Nork et al(45), used fibula plating in achieving distal tibia reduction and acceptable radiographic alignment in 92% of their study patients.

In his article Megas et al(44), inferred that he used fibula plate fixation in all 14 cases in his series to facilitate nail placement with appropriate length and alignment.

A retrospective analysis of 72 fractures by Egol et al(15) assessing malalignment after surgery found that 75% of fracture malreduction occurred when fibula was not stabilised. He also concluded that late malalignment after tibia with fibula stabilization was significantly less (4%) when compared to fractures of tibia where fibula was not stabilized (13%).

In addition Morin et al(59), concluded after a biomechanical investigation using 8 cadaveric specimens of tibia that fibular plating in addition to IM nailing of tibia for distal third tibia fractures offers a small biomechanical advantage in rotation of 1.1 deg at 5 N.M of torque.

Heather Valliers study in 2008(18) on 113 distal tibia fractures treated by plate and nailing revealed the increased incidence of non-union in IM nailing group 12% vs 2.7% in the ORIF group. The non-union was particularly common after concurrent fixation of fibula 14% vs 2.6% when fibula was not fixed. The study group even recommended to use fibula fixation s an aid for tibia reduction during nailing and to remove the fibula fixation once nailing was completed. So the role of fibular fixation in tibial nailing in distal third tibia fractures needs further study.

RETROSPECTIVE STUDIES:

Study	Year	No of fractures	Time to union wks	Malunion %	Non-union %	Infection %
Janssen et al	2006	12	21	50	25	8.3
Yang et al	2006	13	22.6	23	0	0
Im et al	2005	34	18	12	8.8	2.9
Nork et al	2005	30	23.5	8	19	3.3
Obremsky et al	2004	57	14.8	18	8.8	5.3
Dogra et al	2000	15	20	20	20	0
Tylliankas et al	2000	74		0	4.1	1.3
Mosheiff et al	1999	52	15.3	0	4.2	3.8
Robinson et al	1995	63	16.2	6.4	6.4	0

Time to return to work:

Dogra et al in his study observed 5 months as the average time to return to work. Vallier 2012 evaluated and found that 95% of patients returned to work irrespective of plating or nailing. 77% of IM nailing returned to moderate to heavy work vs 71% plating and 31% had modified their work post injury.

Prospective trials:

Vallier et al 2008-11	Malunion %	Non-union %	Infection %
IMN	27.3	9.8	5.3
PLATING	12.9	3.5	4.7

Guo et al 2010	Time to union (weeks)	Infection %	Implant removal %
IMN	17.7	6.8	84.9
PLATING	17.6	14.6	92.7

PATIENTS AND METHODS

86 distal tibia fractures were treated in the Department of Orthopaedics Unit 3 of Christian Medical College, Vellore, South India, from January 2011 to August 2014 including both open and closed injuries, of which 37 patients underwent intramedullary nailing.

	Number of patients
Intramedullary nailing	37
Plating	32
External fixation	16
Nonoperative management	1

INCLUSION CRITERIA:

Patients who sustained extrarticular distal tibia fractures from 4cms – 11cms above the tibial plafond and were treated by intramedullary interlocking nailing were included in the study. Both open and closed fractures were included.

EXCLUSION CRITERIA:

Patients with pathological fractures, stress fractures, paediatric patients (< 14 yrs of age), metabolic bone diseases, distal tibia fractures with intrarticular involvement and patients with extrarticular fractures involved in other interventional studies were all excluded. We excluded 6 patients, 1 patient due to pathological fracture and 5 patients involved in other interventional studies during the same period. There were finally 31 patients included in this study.

Contact details of these patients were retrieved from the inpatient records. All patients were then contacted by phone or post and asked to come for followup in OPD. One patient had expired due to cardiac ailments 7 months post-surgery which was further confirmed by a house visit. 5 patients were lost to follow up. Out of the 31 patients, 25 patients had a minimum of 1year followup and were included in our study.

At followup, consent was obtained from the patients and a detailed clinical examination was done by two examiners independently followed by specific functional scores and measurement of radiographic parameters.

FUNCTIONAL SCORES (CLINICAL ASSESSMENT):

The functional outcome was calculated using a standard set of questions. We used the AOFAS and Olerud and Molander scores.

AOFAS:

The American orthopaedic Foot and Ankle Society Score (AOFAS) introduced Kitaoka et al(60) in 1994. It has nine questions divided into three components.

1. Pain
2. Function
3. Alignment

Total score possible for a patient was 100 points. Alignment of the foot and range of motion of the ankle (measured by orthopaedic goniometer) was completed by the examiner on clinical assessment and assessing the radiographs. The other questions were completed by the patients. The individual scores were then added together to obtain an overall functional score, which was then expressed as a percentage of the normal (100 points).

OLERUD AND MOLANDER SCORE:

The Olerud and Molander score is a self-administered patient questionnaire. The least possible score was 0 (totally impaired) to a maximum possible score of 100 (completely normal). It is based on nine different aspects

1. Pain 2. Stiffness 3. Swelling 4. Stair climbing 5. Running 6. Jumping 7. Squatting 8. Supports 9. Work.

Score	Grade
91-100	Excellent
61-90	Good
31-60	Fair
0-30	Poor

The diagnostic criteria used for clinical assessment for return to work and infection were defined as given below.

Return to work: Six months was chosen as the point at which the patient making an uncomplicated recovery would be expected to return to their normal daily activities.(50)

Infection: Infection was defined as superficial if does not require any secondary procedures and settles with oral antibiotics for 5 days upto 2 weeks. Defined as deep if requires any secondary procedures like debridement or screw removal and not settling with antibiotics for more than two weeks.

RADIOLOGICAL ASSESSMENT:

Radiographic assessment included malalignment, time to union and loss of reduction. Radiographic assessment was done comparing the anteroposterior and lateral views of the affected leg with both the knee and ankle joints included. The varus/valgus angles were calculated by the Paley and Tetsworth method(61). Lines were drawn horizontally over the tibial plateau and tibial plafond. Their midpoints were identified and connected with a vertical line. Then a perpendicular was drawn to the horizontal line over the tibial plafond .The angle formed between the perpendicular and line joining the midpoints of the plateau and plafond was considered as the varus/valgus angle based on lateral or medial angulation respectively. The same method was followed in the lateral view to calculate the procurvatum/recurvatum angles. These angles were calculated from the immediate postoperative radiograph and the final followup radiograph. The residual deformity, malalignment and loss of reduction were noted.

The diagnostic criteria for radiological assessment of distal tibia fractures, consistent bony union, malunion, non-union and delayed union are defined below.

Diagnostic criteria:

Distal tibia fractures: Fracture of the distal 1/3rd of the tibia present 4cms-11cms above the tibial plafond

Consistent bony union: It was defined based on two criteria described by Sarmiento

1. The ability of the patient to bear weight without pain

2. Visible bridging callus on three out of four cortices across the fracture in the AP/lat radiographs.

Malunion: Malunion was defined as

1. Varus or valgus deformity more than 5 degrees

2. An anteroposterior angulation more than 10 degrees

3. A shortening of the limb more than 1 cm.

Delayed union: Delayed union was defined as failure of fracture union by 6 months after surgery.

Non-union: Non-union was defined as failure of fracture union within 9 months of surgery.

SURGICAL TECHNIQUE:

Surgical procedures were performed by either a senior consultant, junior consultant or a post graduate registrar. In all cases surgery was performed in supine position. The injured limb was painted and draped in such a way that it can be left freely hanging down from the side of the operating table. It was ensured that adequate flexion of the knee was possible to achieve central placement of the guide wire without hitting the posterior cortex. Concurrent fibula fixation was done in 9 cases. The decision to fix fibula before tibia nailing or after nailing was under the sole discretion of the operating surgeon . Fibula fixation was done either to achieve alignment of the fracture, achieve length or to increase stability. When fibula was decided to be fixed first, fibula fracture was exposed through a lateral incision.

Fracture was reduced and fixed with 1/3 rd tubular plates or 3.5mm DCP after which the limb was held by the side of the table and the tibial nailing was done. A 5cm skin incision was made from tip of tibial tuberosity extending proximally to the lower pole of patella. The patellar tendon splitting approach was used in all cases. The entry point was made with an awl just below the articular margin of the tibial plateau in lateral view and medial to the lateral tibial spine in anteroposterior view after confirming there was no rotational malalignment of tibia with an image intensifier. Guide wire was passed and fracture reduction was achieved manually. Placement of guide wire in the centre of the medullary canal was achieved by using Poller screws in 14 cases. One or two Poller screws were used as per the on table requirement.

Implants used:

Two types of nails were used. Type of nail to be used was decided by the operating surgeon. One was the conventional tibial nail (AO Simplified Universal Nail S.U.N. ,Switzerland) with two proximal interlocks and two distal interlocks mediolaterally and other was a Zerolock Nail (AO Synthes, Switzerland) with two proximal interlocks and two distal medial lateral locks, 1 antero posterior and 2 oblique interlocks. Minimum of 2 to maximum of 4 distal interlocks were used.

Figure 5: Conventional nail

Figure 6 : Zerolock nail with multiple distal Locking options

Figure 7: Patient positioned supine on the fracture table with leg hanging by the side of the table

Figure 8: Entry point made with an awl and Guide wire passed

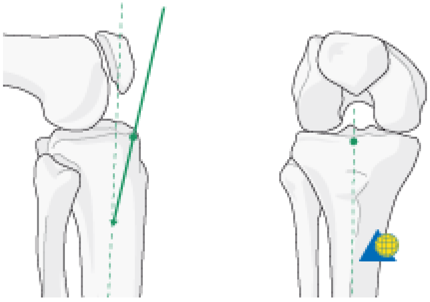

Figure 9:

Entry point is made just below the articular surface in lateral view and just medial to the lateral tibial spine in AP view

Figure 10: Reaming with 0.5mm increments done until clatter occurs at the isthumus

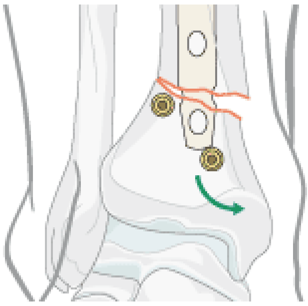

Figure 11: Appropriate size nail is passed. Central location of nail facilitated by Poller screws

Figure 12: Central placement of guide wire and nailing with three distal locking screws placed

Postoperative care:

Antibiotic prophylaxis in the perioperative period included intravenous Cefazolin and Gentamycin for closed fractures. Intravenous Crystalline Penicillin was added if it was an open fracture. Intravenous Ciprofloxacin was used if the patient's age was more than 40 yrs instead of Gentamycin. All intravenous antibiotics were continued for 2 days until drain removal and was started on oral antibiotics for another 5 days. The duration of IV antibiotics were longer on an average upto 10 days (range 5-15 days) if it was a case of open fracture. The patients were discharged from the ward once they were comfortable. They were started on toe-touch weight bearing or nonweight bearing crutch walking as the fracture pattern demanded and were followed up in OPD at regular intervals at 6 weeks,3 months,6 months ,9 months and 1 year interval.

STATISTICAL ANALYSIS:

The collected data was analysed for significant relationships among the studied variables with the help of statistical analysis. The analysis was done with SPSS 16.0 version. Descriptive statistics were given using frequencies with percentages for categorical variables and the mean and the standard deviation were used for continuous variables. To find the difference between the bivariate samples in the independent groups (male and female) unpaired sample T-Test was used. To find the agreement between the scores scatter plot was used. To assess the relationship between the variables Pearson's correlation was used. To find the significance in the categorical data Chi-square test was used. In all the above statistical tools the probability value 0.05 is considered as significant level.

RESULTS

25 Patients who were followed up were included in the study for assessment of functional outcome of intramedullary nailing for their distal tibia extrarticular fractures. One patient had infection during the course of follow up and hence underwent an implant exit followed by orthofix fixation. He was not included for functional outcome assessment. Hence a total of 24 patients were included for final analysis.

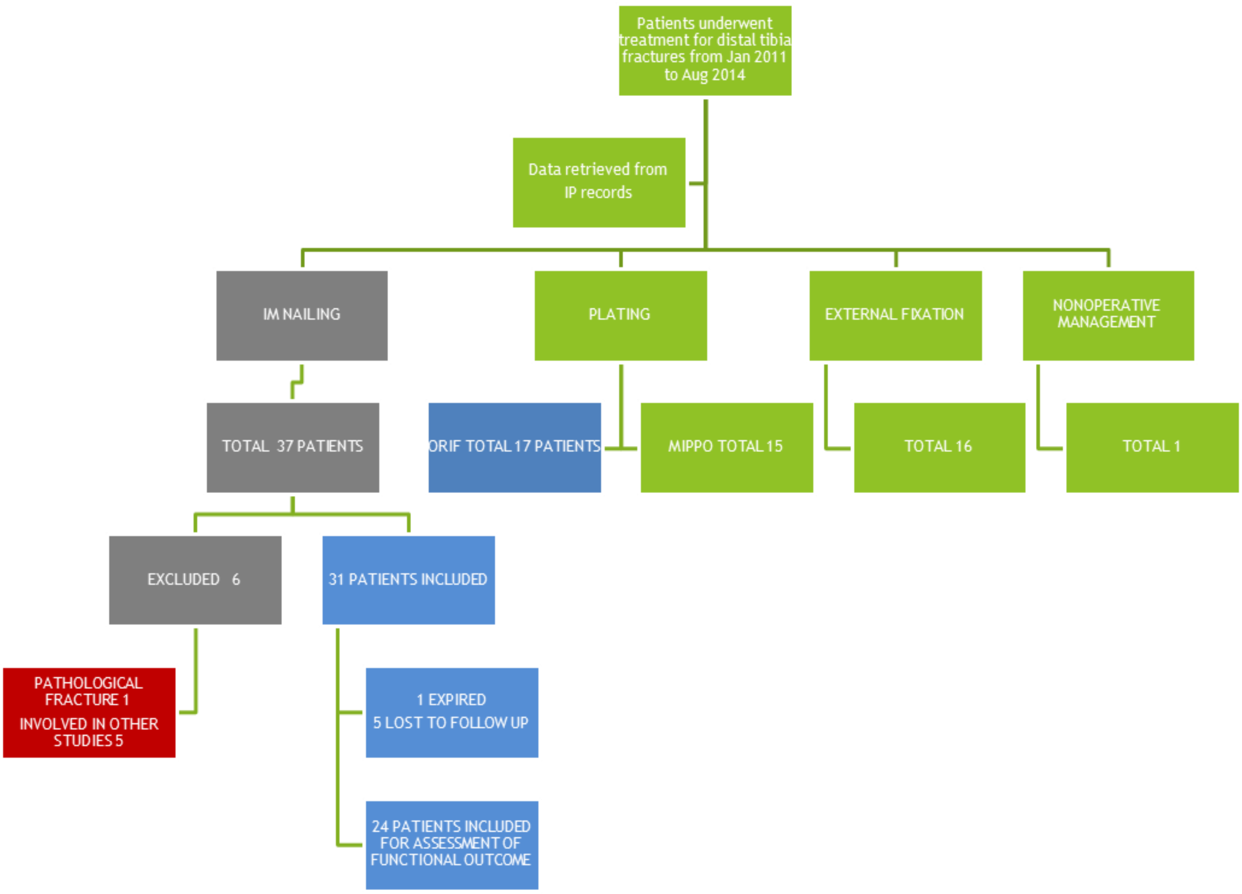

Figure 13: Flow chart showing the method of patient selection for the study.

PATIENT AND INJURY CHARACTERISTICS:

Out of the 25 patients there were 19 males and 6 female patients. The mean age of the patients at the time of injury is 41.29 yrs (range of 19 to 71 yrs). The minimum follow up period was 12 months and maximum of upto 40 months.

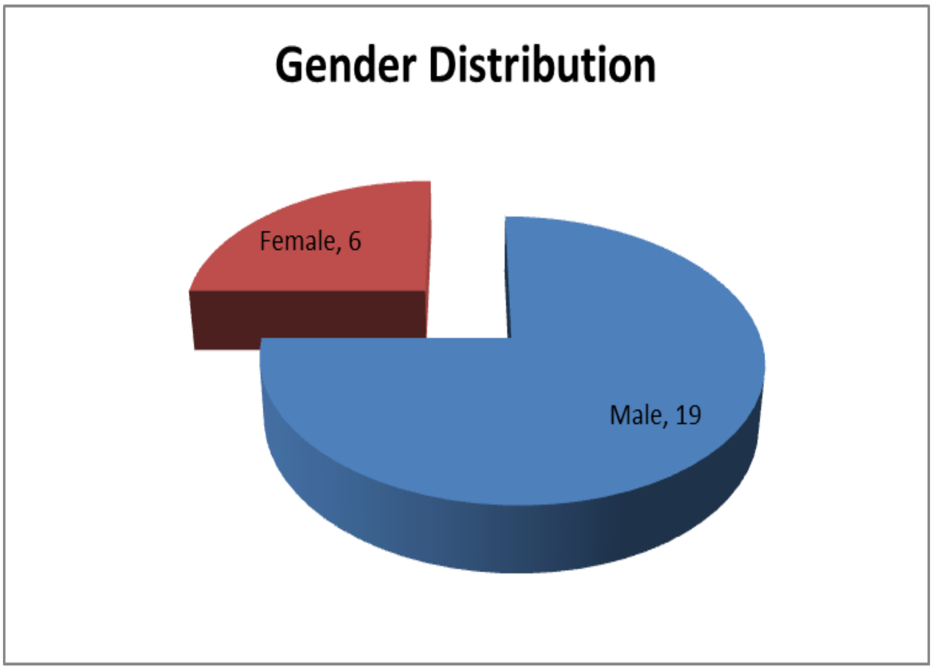

Figure 14. Pie chart showing distribution of sex.

Mechanism of injury was of high energy in 21 patients (84%) and low energy in 4 (16%).

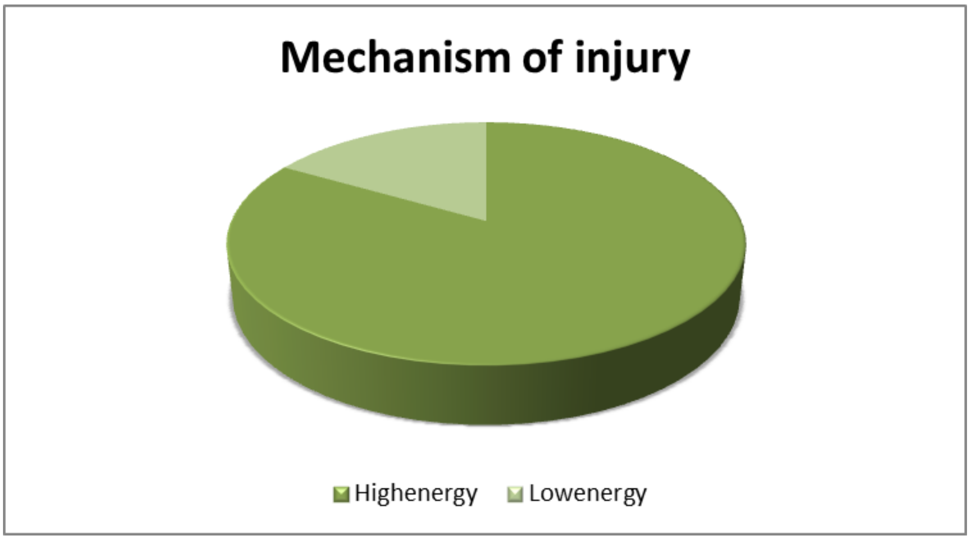

Figure 15: Pie chart showing distribution of mechanism of injury

FRACTURE CHRACTERISTICS:

Out of 25 patients, 15 (60%) had sustained closed fractures and 10 (40%) patients have sustained open fractures. Open fractures were further classified by Gustilo and Anderson’s method.

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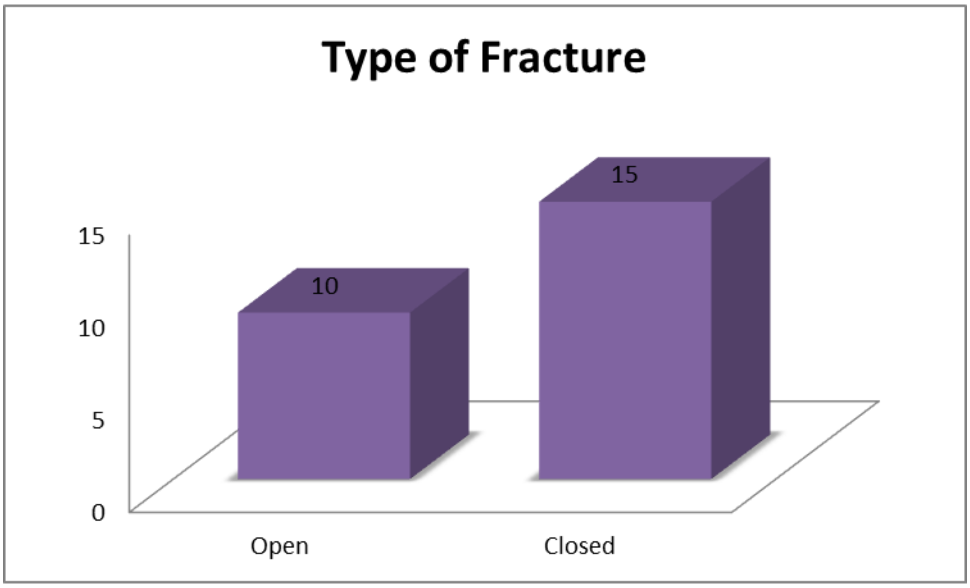


Figure 16: Bar diagram showing distribution of open and closed fractures.

		Open fracture
Gustilo	Type 1	2
	Type 2	1
	Type 3A	2
	Type 3B	5
TOTAL		10

Table 1. Showing number of open fractures and their distribution according to Gustilo classification

Soft tissue injury in closed fractures were graded as per Tscherne –Gotzen grading. The distribution of patients in different grades is shown on the picture below.

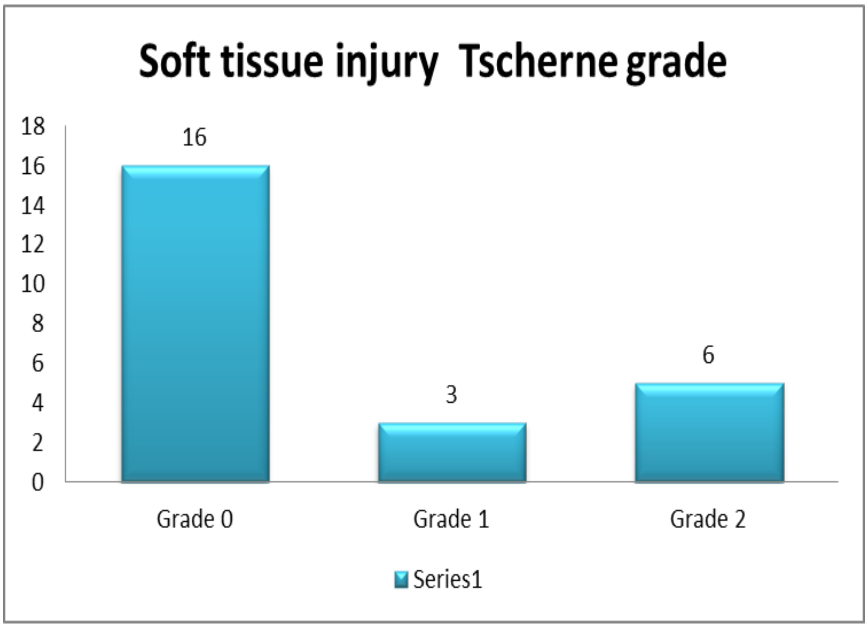


Figure 17: Bar diagram showing distribution of soft tissue injuries according to Tscherne grade

. Type of distal tibia fracture sustained was classified by AO/OTA classification. (Refer annexure 5).Higher percentage of patients had sustained A2 (metaphyseal wedge) type of fracture. Two patients were polytrauma patients sustaining injury to more than 2 organ systems. 22 patients had sustained isolated limb injury

		Frequency	Percentage
AO 43	A 1	8	32.0
	A 2	11	44.0
	A 3	6	24.0
		25	100

Table 2. Showing distribution of distal tibia fractures according to AO classification

Concurrent fibula fracture was present in 83.3 % cases.

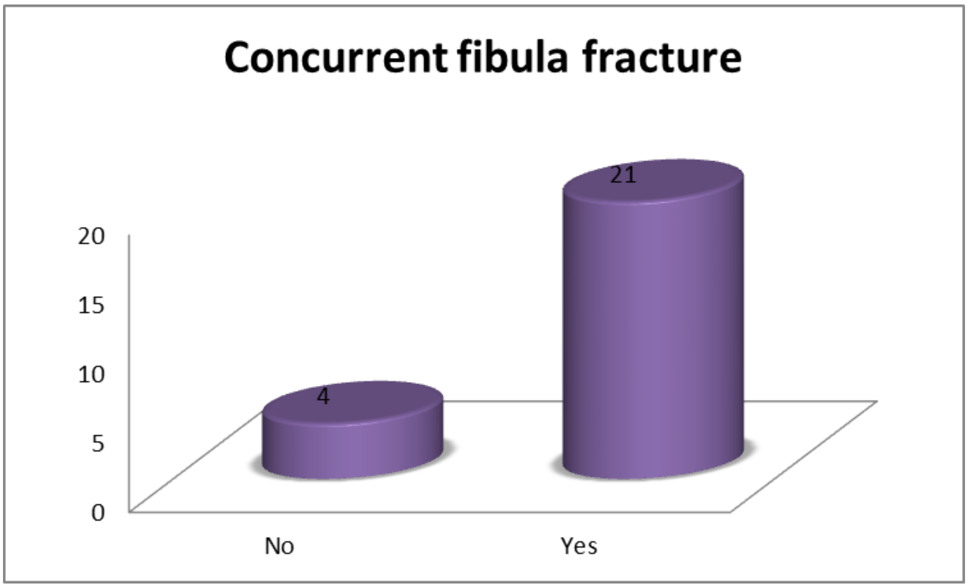


Figure 17: Bar diagram showing distribution of concurrent fibula fracture..

The average time taken to do surgery was 5.58 days (range of 1 day to 15 days). One patient underwent surgery after 53 days due to associated head injury and this value was considered an outlier.

The surgeries were done by senior consultants, junior consultants and PG trainee registrars . The number of surgeries done by each of them is given in the table below.

	Frequency	Percentage
Senior consultant	9	37.5
Junior consultant	10	41.7
PG Trainee	5	20.8

Table 3. Showing distribution of number of cases done by surgeons.

IMPLANT CHRACTERISTICS:

Regarding the usage of implants, conventional nail was used in 40 % cases and zerolock nail with additional distal locking options were used in 60% cases. Analysis revealed that when the distance of from fracture from the tibial plafond was on an average > 8cms conventional tibial nail has been used. Exception was two cases where the distances were 7.8cms and 5.8cms.

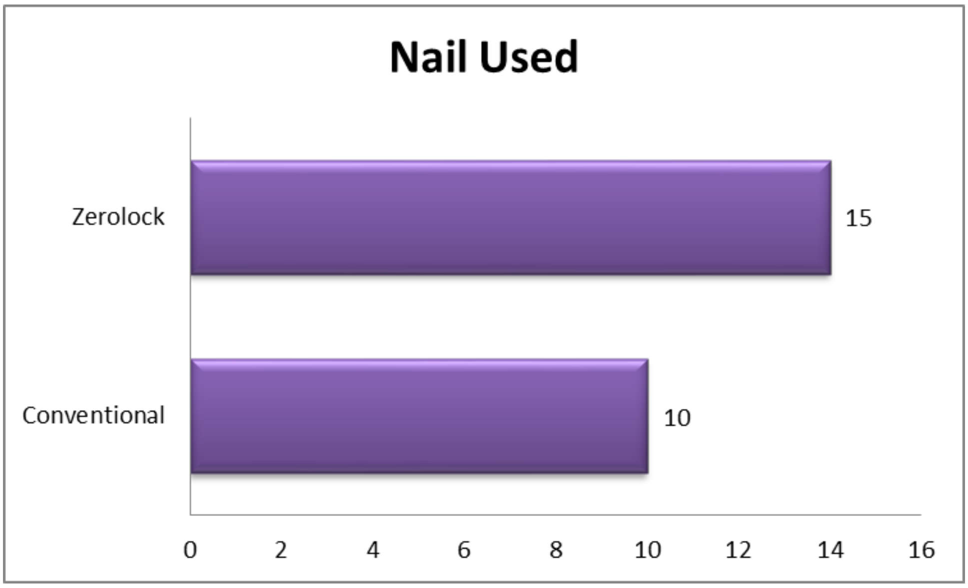


Figure 18: Bar diagram showing distribution of implant used

The total number of distal locks used, number of distal locks used mediolaterally and anteroposteriorly are given in the following table.

		No of cases	Percent
Total no of distal locks used	2	7	29.2
	3	14	58.3
	4	3	12.5
Mediolateral locks	1	10	41.7
	2	14	58.3
Anteroposterior locks	0	5	20.8
	1	8	33.3
	2	11	45.8

Table 4. Showing number of distal locks used

Poller screws were used as a reduction tool and to achieve perfect alignment in 14 cases. 3.5mm cortical screws were used as Poller screws which were left in place after achieving reduction.

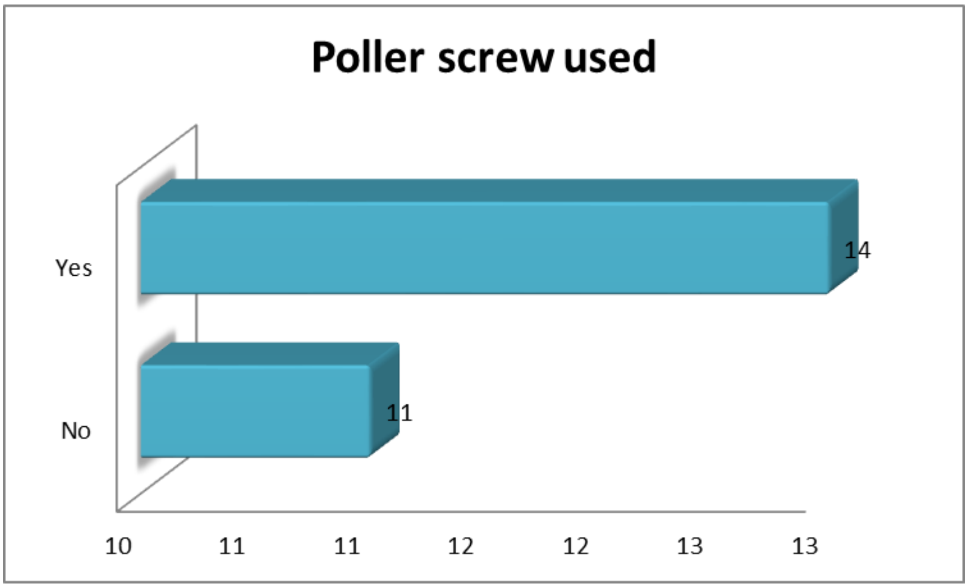


Figure 19: Bar diagram showing distribution of use of Poller screws.

Concurrent fibula fixation was done in 9 cases. Fibula fixation was done with either 3.5 mm DCP or two 1/3rd tubular plates staked over one another.

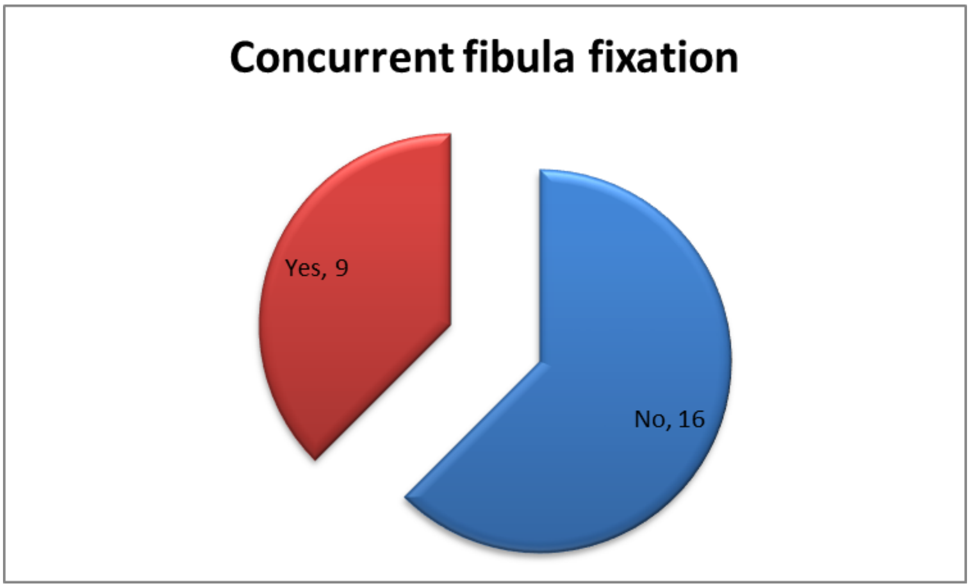


Figure 20: Pie chart showing distribution of cases where fibula fixation was done

RADIOLOGICAL CHARACTERISTICS:

The average distance of fracture site from the tibial plafond was 8.26cms (range of 4cm to10.8cms).It was observed that the fracture site of 9 patients who had valgus malalignment was on an average 8cm from the tibial plafond. The average time taken to radiological union was 19.88 weeks (range of 12 weeks to 34 weeks).

The radiological parameters revealed that none of the patients had a varus deformity in the immediate postop X- ray. The average valgus angle in the immediate post op period was 5.35 degrees (Range of 0 deg to 13.2 degrees). 12 patients had a valgus angle more than 5 degrees.

The final followup X- rays showed 9 patients with valgus angle more than 5 degrees. Out of 9 patients, 5 patients had higher valgus than the immediate post op period indicating a loss of reduction and malunion. The average valgus angle in final follow up period is 4.36 degrees (Range of 0 to 14.8).

The measurement of radiological parameters in the lateral view in the immediate post op period revealed that 2 patients had procurvatum/recurvatum angle more than 10 degrees. The average procurvatum/recurvatum angle was 5.24 degrees (Range of 0 to 14 degrees).

The final follow up X- rays revealed 4 patients with more than 10 degrees of procurvatum/recurvatum angle. All four had higher procurvatum/recurvatum angles than the immediate post op period indicating a loss of reduction or malalignment. The average procurvatum/recurvatum angle in the final followup x-rays were 4.56 degrees (Range of 0 to 16.5 degrees).

Nine patients had final followup radiological parameters suggesting of malunion as per the diagnostic criteria. (Valgus/Varus angle more than 5 degrees in AP view, Procurvatum / Recurvatum angle more than 10 degrees in lateral view).

	Minimum	Maximum	Average	No of patients with valgus > 5 degrees in AP view	No of patients with procurvatum/ recurvatum angle > 10 degrees in lateral view
Valgus angle immediate postop	0	13.2	5.35	12	NA
Valgus angle in followup	0	14.8	4.36	9	NA
Procurvatum/recurvatum in immediate post op	0	14.0	5.24	NA	2
Procurvatum/recurvatum in followup	0	16.5	4.56	NA	4

Table 5.Showing average malalignment angles and number of patients with malalignment

	Average in deg
Valgus immediate postop	8.7
Valgus in follow up	8.9
Pro/Recurvatum in immediate post op	13.35
Pro/Recurvatum in followup	12.47

Table 6. Showing average malalignment angles of patients above acceptable criteria

CLINICAL ASSESSMENT:

The average time taken to partial weight bearing was 11 weeks (range of 2 weeks to 20 weeks). The average time taken to full weight bearing was 18.92 weeks (range of 2 weeks to 40 weeks). The average time taken to return to work was 29.68 weeks (range of 12 weeks to 54 weeks). Two patients did not return to their work. Out of the 24 patients, 9 patients have changed their job or have not returned to their job since they were not able to continue in their previous jobs due to their injury. 15 patients were able to return to their previous jobs without any difficulties.

Functional scores assessment:

The mean AOFAS score was 88.33 (Range of 64 to 100). The mean Olerud and Molander score was 81.25 (Range of 20 to 100).

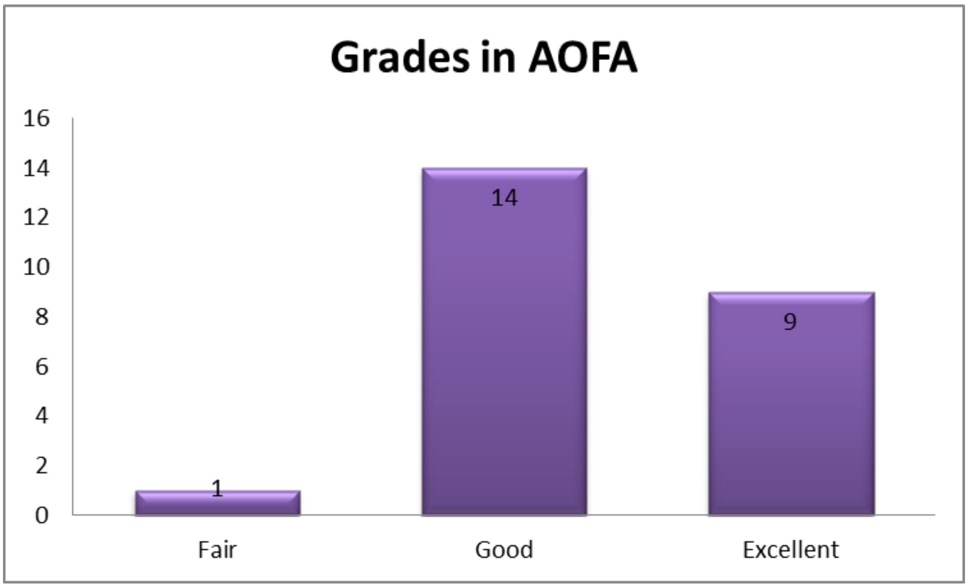


Figure 21: Bar diagram showing distribution of AOFAS

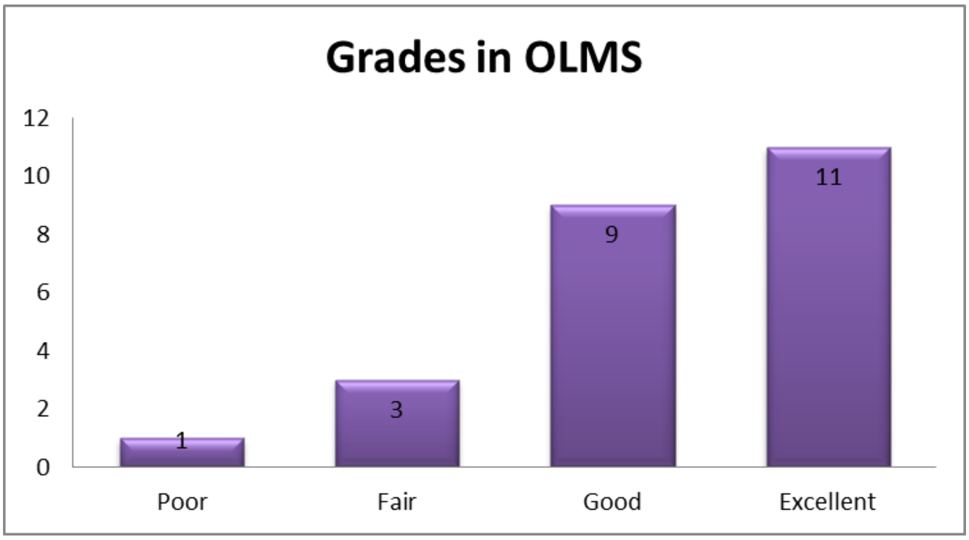


Figure 22: Bar diagram showing distribution of Olerud and Molander score

The table showing mean AOFAS and Olerud and Molander scores in males and females are given below. The results show poor scores for females compared to males.

	Male	Female	Mean
AOFAS	91.27	79.5	88.23
Olerud & Molander	87.77	61.6	81.25

Table 7. Showing mean AOFAS and Olerud Scores.

COMPLICATIONS:

In the followup examination where the minimal followup period was 12 months and maximum followup of upto 40 months with a mean of 26 months, wound healing was 96%. 1 patient was excluded because of wound infection. He sustained an open fracture (Gustilo 3B) for which he underwent intramedullary nailing with Poller screws. During followup his wound infection did not resolve with antibiotics. Hence 5 weeks post-op he underwent nail exit and orthofix fixation. Out of 24 patients, 2 patients had fracture site tenderness, pain on full weight bearing and radiological union of only two cortices out of 4. Those 2 patients were considered as non-union.

Wound infection	1
Fracture site tenderness, Pain on FWB	2

4 patients underwent additional procedures. Mostly for their soft tissue cover in the form of split thickness skin grafting except for one patient who underwent bone grafting in addition to skin grafting for a metaphyseal bone loss 1 month after the intramedullary nailing. His fracture united uneventfully.

		Frequency	Percentage
Additional Procedures	No	20	83.3
	Yes	4	16.7

Table 8. Showing number of patients who underwent additional procedures.

Out of the 24 patients 7 (29.2%) patients had implant related pain. 4 patients (16.3%) underwent implant exit (3 patients underwent nail removal and 1 patient underwent distal screw removal).1 patient had re-fracture due to a fall 11 months post-surgery and underwent exchange nailing. Two patients underwent redo nailing in the immediate post op period due to malreduction of the fracture.

Complications	Number of patients	Percentage
Malunion	9	37.5%
Non-union	2	8.0%
Implant related pain	7	29.2%
Implant removal	4	16.7%
Infection	1	4%

Table 9. Showing complications and percentage

STATISTICAL ANALYSIS:

The correlation between the variables measured and the scores were analysed using sample T-Test. There was significant correlation between both the functional scores with sex of the patient. It was observed that female patients performed poorly compared to male patients. There was significant correlation between age and Olerud score. The other variables like time to return to work and degree of malalignment did not correlate significantly with the scores which is given in the table below.

Variables	AOFAS r (p-value)	Olerud score r (p-value)
Age	-0.12 (0.57)	-0.42 (0.04)
Sex	-0.51 (0.01)	-0.56 (0.004)
Time to PWB	-0.07 (0.74)	-0.13 (0.53)
Time to FWB	-0.19 (0.36)	-0.15 (0.46)
Time to return to work	0.02 (0.934)	-0.11 (0.64)
Radiological union	-0.01 (0.95)	0.17 (0.42)
Valgus in followup	0.001 (0.99)	-0.07 (0.76)
Pro/recurvatum in followup	-0.19 (0.35)	-0.22 (0.28)
Fibula fracture	0.07 (0.73)	0.03 (0.89)

Table 10. Showing correlation between variables and scores

The sample T-test was also used to identify associations between other possible predictive variables like fibula fixation and radiological union, use of Poller screws with post-operative varus/valgus malunion. The analyses showed no significant correlation between the variables which is shown in the table below.

	Fibula fixation		**p-value**
	FALSE Mean (SD)	**TRUE Mean (SD)**	
Radiological union	19.73 (5.86)	20.11 (4.96)	0.87
Immediate post op valgus malalignment	6.09 (3.59)	4.12 (4.36)	0.24
Followup varus valgus malalignment	4.9 (4.38)	3.47 (3.96)	0.43

Table 11. Showing correlation between fibula fixation with different variables

	Use of Poller screws		**p-value**
	FALSE Mean (SD)	**TRUE Mean (SD)**	
Immediate post op valgus malalignment	5.3 (3.6)	5.4 (4.3)	0.95
Followup varus valgus malalignment	3.5 (3.3)	5.1 (4.8)	0.38

Table 12. Showing correlation between Poller screws and valgus malalignment

Significant correlation was found between valgus malunion and radiological union. Patients with high valgus malalignment i.e. more than the acceptable criteria of 5 degrees are prone for delayed radiological union than patients with acceptable limits of malalignment.

	Valgus malalignment in followup r (p-value)	**Pro/recurvatum in followup r (p-value)**
Time to radiological union	0.43(0.03)	0.04 (0.86)

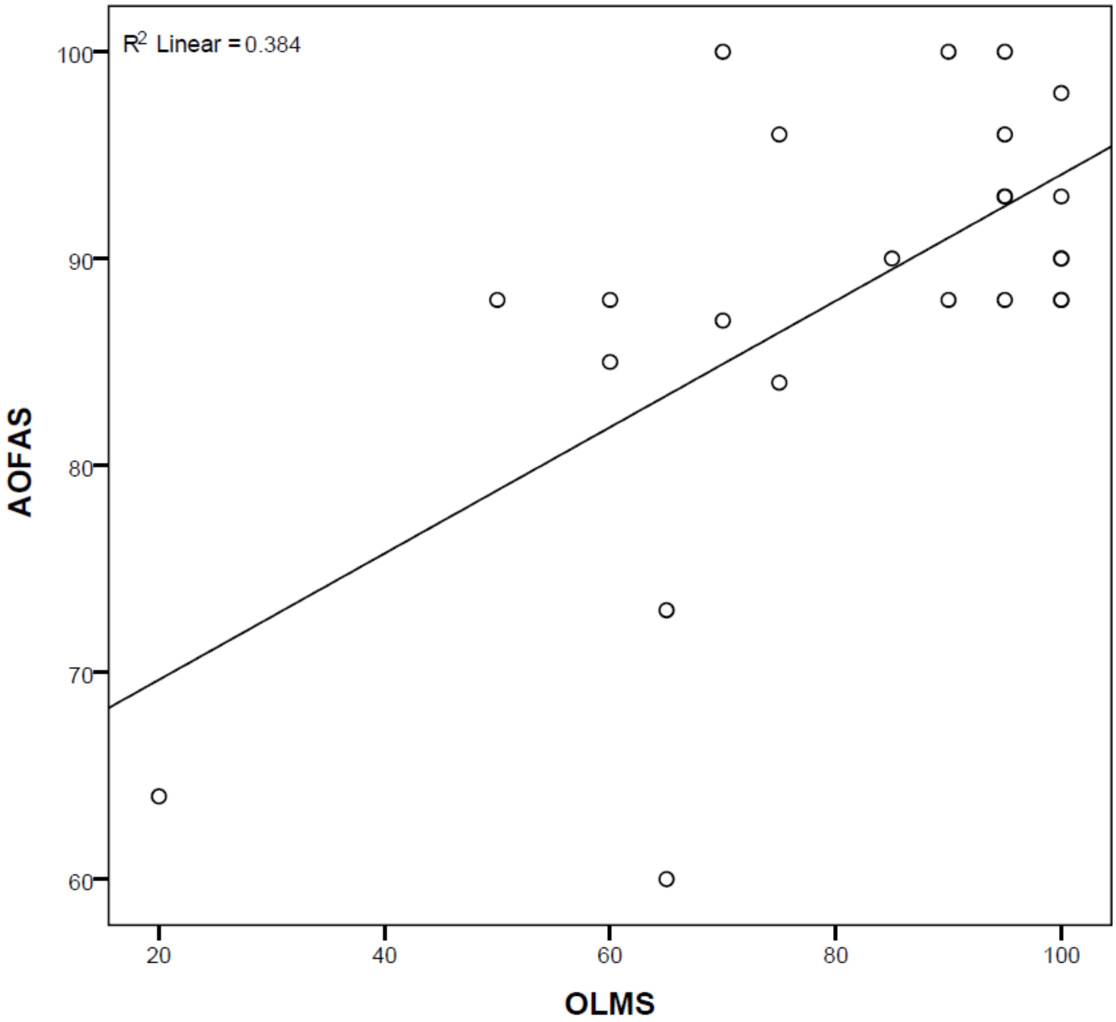
Table 13. Showing correlation between radiological union and malalignment

Patients serial number	Immediate post op valgus angulation (deg)	Followup valgus angulation (deg)	Time to radiological union in weeks
2	11.2	14.8	**34**
4	6.7	2.1	**24**
8	13.2	12.0	17
9	12.0	7.0	18
12	9.0	11.7	**28**
13	10.0	3.3	**24**
14	6.8	6.0	**28**
17	5.4	2.2	20
20	8.2	3.0	20
21	6.6	7.3	12
24	8.0	6.0	**24**
25	6.8	2.4	16

Table 14.Showing increased time to radiological union in patients with increased malalignment

It was observed that valgus malalignment was found more frequently in patients with more lateral communition. Similarly patients with more posterior communition presented with procurvatum deformity. To note one patient with anterior communition developed a recurvatum deformity.

SCATTER PLOT:



The agreement between the two functional scores was analysed with scatter plot. The results showed strong agreement between both the scores.

	r (p-value)
AOFAS vs Olerud score	0.62 (0.001)

Table 15. Showing agreement between AOFAS and Olerud and Molander score.

ILLUSTRATIVE CASES

ILLUSTRATIVE CASES

CASE 1

32 yr old male with alleged history of road traffic accident, high energy injury, sustained an open fracture Gustilo type 1 to the left lower limb. The fracture was classified as AO type 43 A1. The fracture was stabilized with zerolock nail for the tibia and open reduction and internal fixation with plate and screws for the fibula. Poller screws were used to achieve good alignment and reduction. Radiologically callus was evident by 12 weeks. His ankle range of movement during final followup (32 months) was 20 degrees of dorsiflexion and 30 degrees of plantarflexion. He did not have any limb length discrepancy. His AOFAS and Olerud scores were excellent.

Figure 24: Showing Preop AP/Lateral views of the patient (case 1)

Figure 25: AP/LAT view in immediate post op (case 1)


Figure 26: AP/LAT views during last follow-up (case1)

Figure 27: Clinical pictures of patient showing good ankle range of movements and Squatting (case 1).

CASE 2:

67 yr old male, history of Road traffic accident, sustained a closed injury to the left lower limb. Fracture was classified as AO type 43 A2. Fracture was stabilized with zerolock nail. Poller screws were used to achieve perfect alignment and reduction. His fracture consolidated in 12 weeks. Returned to work in 40 weeks. His ankle dorsiflexion was 20 deg, plantar flexion was 25 deg. His AOFAS and Olerud scores were excellent.

Figure 28: showing Preop AP/LAT views (case 2)

Figure 29: AP/LAT views in immediate post op (case 2)

Figure 30: AP/LAT views during last followup (case 2)

Figure 31: Clinical photos showing Plantigrade ankle and sitting cross-legged (case 2)

CASE 3:

58yr old male, history of fall, low energy injury, sustained closed fracture distal tibia right leg. Fracture was classified as AO 43 A2. Fracture was stabilized with zerolock nail and Poller screws were used to prevent malalignment of the fracture. Achieved radiological union in 20 weeks and returned to work in 32 weeks. He had no varus or valgus malalignment. His AOFAS and Olerud scores were excellent.

Figure 32: Preop AP/LAT views (case 3)

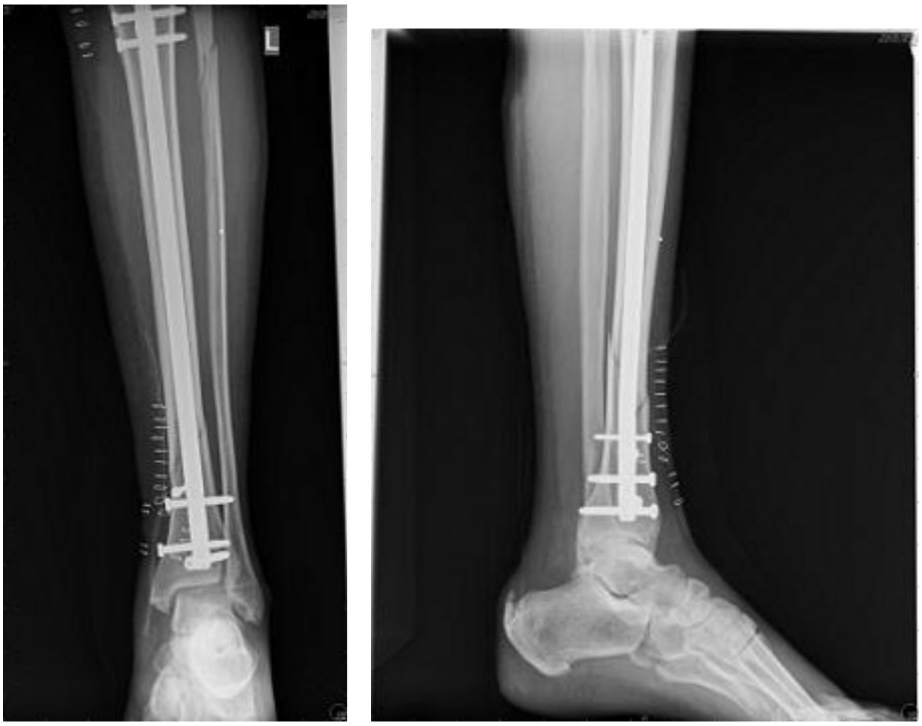


Figure 33: Immediate post op AP/LAT (case 3)

Figure 34: 1 yr follow-up AP/LAT (case 3)

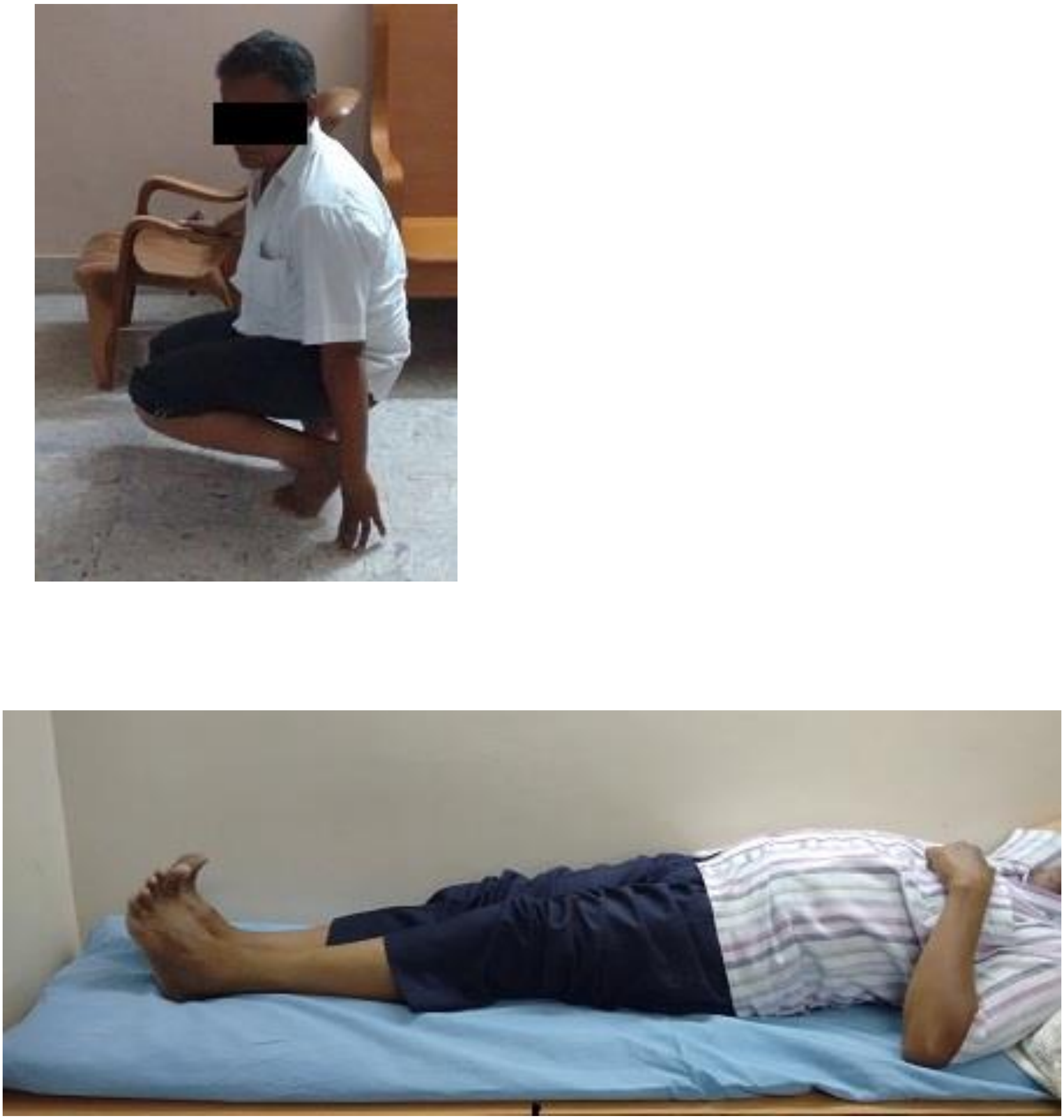


Figure 35: Showing ability to squat and dorsiflex. (Case 3)

Figure 36: Clinical photos showing good range of ankle dorsiflexion and plantarflexion of another patient

CASE 4:

71yr old female, low energy injury, sustained closed fracture to the left lower limb. Underwent intramedullary nailing 2 days post injury. During followup she complained of pain on partial weight bearing at 6 weeks. She had difficulty in walking for activities of daily living. Her Olerud score was 60 (fair). Her radiographs revealed both valgus and procurvatum deformity with signs of union in only one cortex. She was considered as non-union as per the diagnostic criteria.

Figure 37: Showing Preop ap/lat views

Figure 38: Showing follow-up X-ray at 1 yr with valgus and procurvatum deformity

	N	Minimum	Maximum	Mean	Std. Deviation
AGE (yrs)	24	19	71	41.29	15.347
TIME TO SURGERY (days)	24	1	53	5.58	10.620
DISTANCE FROM TIBIAL PLAFOND (cms)	24	4.0	10.8	8.263	1.9217
VALGUS IN IMMEDIATE POSTOP (deg)	24	0.0	13.2	5.354	3.9251
VALGUS IN FOLLOWUP (deg)	24	0.0	14.8	4.363	4.1992
PRO/RECURVATUM IN IMMEDIATE POSTOP (deg)	24	0.0	14	5.24	3.455
PRO/RECURVATUM IN FOLLOWUP (deg)	24	0.0	16.5	4.546	4.2164
RADIOLOGICAL UNION (wks)	24	12	34	19.88	5.432
TIME TO PARTIAL WT BEARING (wks)	24	2	20	11.00	5.748
TIME TO FULL WEIGHT BEARING (wks)	24	2	40	18.92	9.564
TIME TO RETURN TO WORK (wks)	22	12	54	29.68	11.982
AOFAS (max 100)	24	60	100	88.33	10.120
OLERUD SCORE (max 100)	24	20	100	81.25	20.550

Table 16. Showing average of different variables.

DISCUSSION

The advantages of intramedullary nailing compared to other forms of fixation like plating and external fixation in tibial fractures alone cannot support the use of intramedullary nailing in distal tibial fractures of tibia. The problems of extending the indication to use in extrarticular metaphyseal fractures of tibia should be analysed and addressed for coming out with excellent functional outcomes.

The amount of malalignment considered as malunion in the diagnostic criteria in this study is controversial. Because the anteroposterior angulation of upto 10 degrees are not considered as malalignment in this study. But this recommendation by Trafton(62) (acceptable malalignment is < 5 degrees of varus-valgus angulation, <10 degrees of anteroposterior angulation, 10 degrees of rotation and 15mm of shortening) considered in this study is generally agreed by many authors. In our study there is malalignment in nearly 9 out of the 24 cases (36%).

Pynsent (63) suggested that tibial fractures at any location with more than 5 degrees of deformity will result in radiographic changes in the ankle. Van der schoot (47) study of 88 patients with 15 yr followup also revealed that more arthritis was found in the ankle joint adjacent to the fracture than compared to the ankle in uninjured limb. Puno et al (64) observations also confirmed that poorer clinical results are associated with malaligned fractures of tibia.

Kyro(65) in his article of 64 tibial shaft fractures concluded that malunion of tibial shaft fractures seems to produce more complications in distal tibia fractures, in fractures with marked previous displacement, in fractures caused by high energy injury and in patients age > 45 yrs.

The functional outcomes assessed, when analysed, revealed the fact that worse functional outcomes were not related with age or associated injuries. It was associated with the quality of reduction of the fracture. The significant clinical correlation of radiological union with valgus malalignment in our study proves this fact. The mean time to radiological union after IM nailing for distal tibia fractures was in a range 17.7-22.6 weeks (54). The mean time to radiological union in our study is 19.88 weeks. This is well within the range recommended in the literature. The radiological union of fractures of patients with more valgus malalignment were comparatively delayed. This explains the need for perfect alignment of fracture intraoperatively to achieve better functional outcomes. This perfect alignment can be achieved by several means. But use of Poller screws is one simple method with no extra inventory needed and no need for any modification in the nail with less soft tissue compromise. The increased rate of malalignment thus can be controlled.

The overall patient satisfaction is always related to improved physical function and ability to return to work. This applies to population all over the world. In Indian population particularly patients and their dependants are more eager to know on their time to return to job or functional normality than knowing the type of treatment they are going to receive. In this context our study has showed a mean time to return to work as 29.68 weeks (4.24 months). This is comparatively less time when considering both open and closed tibial fractures. Literature(43) has given an average of 5 months' time to return to work of patients who underwent nailing for distal tibia fractures. It has also been reported that nearly 95 % of patients have returned to their work post distal tibia fractures no matter what the type of fixation was(66). Out of which 70 % had returned to moderate to heavy jobs which they were previously performing before the injury(19). Our study has shown that nearly 91.6% of patients had returned to work (22 out of 24), 62.5% of patients had returned to their previous jobs and 37.5% had changed their jobs post injury.

The AOFAS Olerud and Molander scores have performed well in estimating the functional outcome in our study. There was significant correlation between both the scores. Both the scores had significant correlation with age, Olerud and Molander score had additional significant correlation with sex. Women performed poor and had low scores compared to men (Table 10). This was comparable to be Valliers study in 2011(19) where functional scores of women were poor .

The incidence of implant related pain in our study is 29.2 % and 16.5 % of patients had undergone implant exit. The literature gives a 16%(55) incidence of implant exit after tibia nailing in distal tibia fractures. Anterior knee pain was the most common complaint for implant removal apart from prominence of distal locking screw in one patient.

The rate of non-union in IM nailing of distal tibia fractures is 5.5 % (51). Two patients had nonunion in our study (8.0%). The fracture was well aligned within acceptable limits during immediate postop. There was no evidence of any infection. The patient's ankle scores were fair. The incidence of infection in our study was

4%.This explains the advantage of IM nailing over plating in distal tibia by open reduction or MIPO. The rate of incidence of infection in literature in IM nailing is 4.3%(51).

There was no statistical correlation between fibula fixation and radiological union. Out of 9 patients in whom fibula was fixed nearly 3 had postop valgus malalignment. The use of Poller screws also had no statistical correlation with varus/ valgus or procurvatum/recurvatum malalignment. But nearly 13 patients needed Poller screws to achieve acceptable alignment. Out of the 13 in whom Poller screws were used 6 patients had valgus malalignment more than 5 degrees. There should be more studies on the use of fibula fixation and Poller screw use to determine their role in distal tibia fracture fixation.

This study shows that intramedullary nailing is associated with malalignment which may be related to a learning curve when using Poller screws. It also showed that alignment should be carefully checked during the procedure to reduce the rate of malalignment.

LIMITATIONS OF THE STUDY

Limitations of our study are first this is a retrospective study. We prospectively followed up a retrospective cohort where there may not be a balance between the selection of subjects. Secondly the sample size is low to achieve statistically significant correlations. Third the patients were followed up upto 40 months post op. Hence there was definitively a recall bias on when partial weight bearing was started and when full weight bearing was started. Fourth the preoperative X-rays and immediate post op X-ray were not adequately showing the proximal knee joint for malalignment angle measurement. In such case we used the midpoint of the shaft as reference for upper end and midpoint of plafond as reference for lower end.

CONCLUSION

The hypothesis of our study is that intramedullary nailing in distal tibia fractures achieve consistent union and earlier return to work. This objective has been achieved. However there is a high rate of complication in terms of malalignment. This indicated the need for more prospective trials before considering intramedullary nailing as the treatment of choice for extrarticular distal tibia fractures.

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ANNEXURE 1:

IRB APPROVAL
FORM:

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA.

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Alfred Job Daniel, D Ortho, MS Ortho, DNB Ortho
Chairperson, Research Committee & Principal

Dr. Nihal Thomas,
MD., MNAMS., DNB (Endo), FRACP (Endo), FRCP (Edin), FRCP (Glasg)
Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

November 08, 2014

Dr. Sribalaji Prabhu. T
PG Registrar
Department of Orthopaedics Unit 3
Christian Medical College, Vellore 632 004

Sub: **Fluid Research Grant Project:**
Functional outcome of extra articular distal tibia fractures treated by intramedullary interlocking nailing.
Dr. Sribalaji Prabhu..., Orthopaedics Unit 3, Dr. Thilak S. Jepegnanam,
Dr. Boopalan PRJVC, Dr. Viju Daniel Varghese, Orthopaedics,
Dr. B. Antonisamy, Biostatistics, CMC, Vellore.

Ref: IRB Min No: 9100 [OBSERVE] dated 06.10.2014

Dear Sribalaji Prabhu. T,

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Nihal Thomas, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

Dr. NIHAL THOMAS
MD.MNAMS.,DNB(Endo),FRACP(Endo),FRCP(Edin),FRCP(Glasg)
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc. Dr. Thilak S. Jepegnanam, Orthopaedics, CMC, Vellore.

1 of 5

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
Tel : 0416 - 2284294, 2284202 Fax : 0416 - 2262788, 2284481 E-mail : research@cmcvellore.ac.in

ANNEXURE 2: DISTAL TIBIA PROFORMA

PERSONAL , DEMOGRAPHIC DATA AND HOST CLASSIFICATION:

HOSPITAL ID:	AGE:	SEX: MALE /FEMALE	PLACE:
COMORBIDITIES: DIABETES / SMOKING / OSTEOPOROSIS / STEROID INTAKE			
HOST CLASSIFICATION: HOST A / HOST B / HOST C			

FRACTURE CHARACTERISTICS:

MECHANISM OF FRACTURE: HIGH ENERGY/LOW ENERGY
TYPE OF FRACTURE : CLOSED / OPEN (GUSTILO TYPE 1 , TYPE 2. TYPE 3A , 3B, 3C)
PATTERN OF TIBIAL FRACTURE: AO TYPE 43 A 1 , A 2, A 3.
CONCURRENT FIBULA FRACTURE : YES /NO
SOFT TISSUE INJURY : TSCHERNE-GOTZEN GRADE 0,GRADE 1, GRADE 2, GRADE 3
ASSOCIATED POLYTRAUMA: YES / NO

SURGERY DETAILS:

TIME FROM INJURY TO SURGERY : OPEN FRACTURES: CLOSED FRACTURES:
IM IL NAILING AS PRIMARY PROCEDURE / SECONDARY PROCEDURE
SURGERY: 1.OPERATED BY: SENIOR CONSULTANT/ JUNIOR CONSULTANT/ PG TRAINEE 2.CONCURRENT FIXATION OF FIBULA: YES /NO 3.ADDITIONAL PROCEDURES : YES / NO 4.IMPLANT USED: CONVENTIONAL NAIL / ZERO LOCK NAIL 5.POLLER SCREW : YES / NO 6.NUMBER OF DISTAL LOCKING SCREWS : 2 / 3 / 4 7.MEDIOLATERAL SCREWS: ANTEROPOSTERIOR SCREWS:

CLINICAL EXAMINATION:

ABLE TO FULL WEIGHT BEAR WITHOUT PAIN	YES / NO
FRACTURE SITE TENDERNESS	PRESENT / ABSENT
WOUND STATUS	INFECTED / HEALED
ANY SHORTENING	YES / NO IF YES : CMS
ANKLE ROM	DORSIFLEXION: PLANTARFLEXION:

RADIOLOGY: DISTANCE OF FRACTURE FROM TIBIAL PLAFOND: CMS

	VARUS/VALGUS ANGULATION WITH DEGREE	AP ANGULATION PRESENT /ABSENT WITH DEGREE
INITIAL X RAY AT TIME OF INJURY		
IMMEDIATE POST OP		
FINAL FOLLOW UP		

TIME TO RADIOLOGICAL UNION: WEEKS

INFORMATION FROM THE PATIENT:

TIME TO PARTIAL WEIGHT BEARING	WEEKS
TIME TO FULL WEIGHT BEARING	WEEKS
AVERAGE TIME TAKEN TO RETURN TO WORK	WEEKS
CHANGE IN OCCUPATION	YES / NO

COMPLICATIONS:

1. MAJOR: INFECTION : YES/NO
   SOFT TISSUE DEFECTS REQUIRING FLAP COVER : YES/NO
   NONUNION: YES/NO
   IMPLANT FAILURE: YES/NO
2. MINOR: ANKLE STIFFNESS : YES / NO
   IMPLANT RELATED PAIN: YES /NO

IMPLANT EXIT DONE: YES/NO

FUNCTIONAL SCORES:

	SCORE
AOFAS	
OLERUD AND MOLANDER	

ANNEXURE 3: AOFAS QUESTIONNAIRE

AOFAS Clinical Rating System Ankle- Hind foot Scale (Total 100 points)

Parameter	Scores
1.Pain (score: 40)	
None	40
Mild, occasional	30
Moderate, daily	20
Strong, almost always present	0
2. Function (score: 50)	
2.1 Activities restraint and need of support	
No restraints or supports	10
No daily activities restraint, recreational restraint, no supports	7
Daily and recreational activities restraint, cane	4
Major daily activities restraint, crutches, walker, wheelchair	0
2.2 Maximum gait distance (blocks)	
More than 6	5
From 4 to 6	4
From 1 to 3	2
Less than 1	0
2.3 Gait surface	
Easy in any surface	5
Some difficult in irregular grounds, stairs or slopes	3
Strong difficult in irregular grounds, stairs or slopes	0
2.4 Gait abnormality	
None or mild	8
Evident	4
Marked	0
2.5 Saggital mobility (flexion + extension)	
Normal or minimal restraint (30º or more)	8
Moderate restraint (15º to 29º)	4
Strong restraint (less than 15º)	0
2.6 Hindfoot mobility(inversion and eversion)	
Normal or minimal restraint (75 to 100%)	6
Moderate restraint (25 to 74%)	3
Strong restraint (less than 25%)	0
2.7 Ankle and hindfoot stability (anteroposterior + varus-valgus)	
Stable	8
Unstable	0
3. Alignment (score:10)	
Good – plantigrade foot, with aligned ankle and hindfoot	10
Fair - plantigrade foot, some degree of non-alignment, no pain	5
Bad – non-plantigrade foot, major and symptomatic non-alignment	0

***Chart 1** - AOFAS (American Orthopaedic Foot and Ankle Society) scale for clinical evaluation of the ankle and hindfoot*

ANNEXURE 4:

OLERUD AND MOLANDER SCORE QUESTIONNAIRE

1. Please indicate when you experience pain:

A. Never	25
B. Only while walking on an uneven surface	20
C. Only while walking on even surface outdoors	10
D. Only while walking indoors	5
E. Constant and severe	0

2. Please indicate the degree of stiffness you are experiencing

A. None	10
B. Stiffness	0

3. Please indicate the degree of swelling you are experiencing

A. None	10
B. Only evenings	5
C. Constant	0

4. Please indicate the degree of difficulty with stair climbing

A. No problems	10
B. Impaired	5
C. Impossible	0

5. Please indicate the degree of difficulty with running

A. Possible	5
B. Impossible	0

6. Please indicate the degree of difficulty with jumping

A. Possible	5
B. Impossible	0

7. Please indicate the degree of difficulty with squatting

A. No problems	5
B. Impossible	0

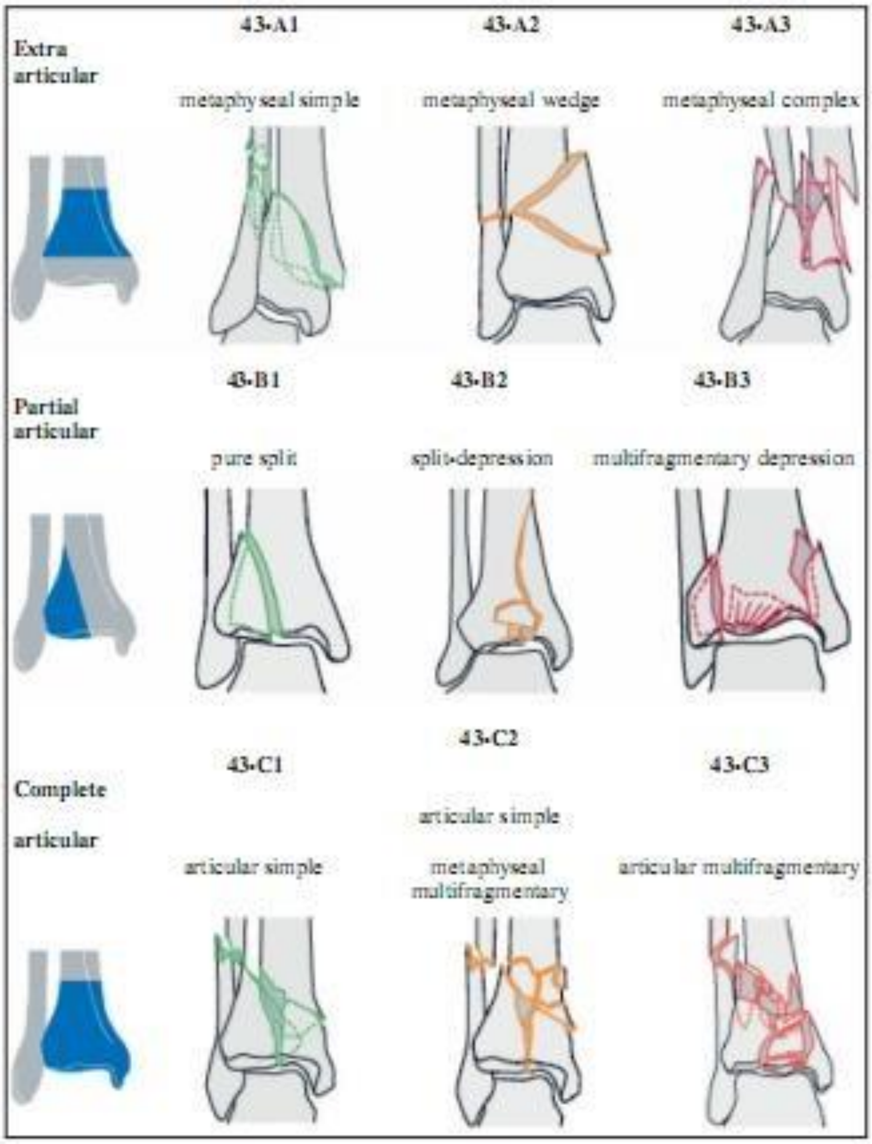
8. Please indicate the type of supports you are currently using

A. None	10
B. Taping, wrapping	5
C. Stick or crutch	0

9. How is this injury affecting your work and activities of daily life?

A. Same as before injury	20
B. Loss of tempo	15
C. Change to a simpler job/part time work	10
D. Severely impaired work capacity	0

ANNEXURE 5: AO CLASSIFICATION OF DISTAL TIBIA FRACTURES



ANNEXURE - 6

INFORMATION SHEET

STUDY TITLE: FUNCTIONAL OUTCOME OF EXTRARTICULAR DISTAL TIBIA FRACTURES TREATED BY INTRAMEDULLARY NAILING:

1.What is this study about?

The incidence of road traffic accidents are increasing worldwide. Fractures are one of the commonest injuries following road traffic accidents. Tibia especially is more prone for injuries due to its subcutaneous location. Less soft tissue and muscle coverage with poor vascularity of distal tibia pose a challenge to the treating surgeons. Researches are going on worldwide to find an appropriate implant to achieve high union rate with less deformity and complications. You are requested to participate in this study which is done to find out the functional outcome of intramedullary interlocking nailing in extraarticular distal tibia fractures.

2.Why I am being chosen for this study?

You are being chosen because you are one among the patients who underwent intramedullary nailing for an extraarticular distal tibia fracture.

3.what will I have to do when I take part in this study?

You have to undergo a set of X-ray films of the treated limb. You will be examined by two examiners regarding your present clinical status of the limb. You will have to answer two questionnaires regarding your present functional status.

4.Do I have any risk in participating in this study?

You absolutely have no risk in participating in this study.

5.Do I have any benefits in participating in this study?

You do not have any direct benefits from participating in this study but indirectly the results of the study will benefit patients who sustain similar fractures in future.

6.Will my personal details kept confidential?

The data collected from you will be protected in secured files with passwords and will not be accessible to anyone except the investigators. You can contact the principal investigator anytime you wish regarding any queries on your participation through phone or in person or via email id given below.

7.Can I withdraw from the study at any part of time?

Your participation is voluntary .You can withdraw from the study at anytime and this will not affect the benefits for which you are entitled.

ANNXURE - 7

INFORMED CONSENT FORM

Study Title: FUNCTIONAL OUTCOME OF EXTRAARTICULAR DISTAL TIBIA FRACTURES TREATED BY INTRAMEDULLARY NAILING.

Name of the principal investigator:

Subject's Name: ____________________Age: ________________________

(i) I confirm that I have read and understood the information sheet . I have had the opportunity to ask questions.

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

(iii) I understand that the Principal investigator, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

(v) I agree to take part in the above study.

Date: _____/_____/______

Signature (or Thumb impression) of the Subject

Study investigator's name: Signature: ______________________

Witness name: Signature or thumb impression: ____________________

ANNEXURE - 8

ஒப்புதல் அறிவிப்பு

ஆய்வின் தலைப்பு:: கணுக்கால் மூட்டுக்கு மேல் ஏற்படும் எலும்பு முறிவுக்கு கம்பி பொருத்தி சிகிச்சை அளிப்பதனால் ஏற்படும் விளைவுகள்

ஆய்வு உறுப்பினர்கள்:

ஆய்வில்பங்கேற்பவர் பெயர்: **வயது**:

1. இந்த ஆய்வின் தகவல் தாளை படித்து புரிந்து கொண்டேன். எனக்கு கேள்விகள் கேட்க வாய்ப்பு அளிக்கப்பட்டது.

2. இந்த ஆய்வில் எனது பங்கேற்ப்பு முற்றிலும் சுயமானது. எனது சிகிச்சை மற்றும் சட்டரிதியான உரிமைகள் பாதிக்கபடாது. இந்த ஆய்விலிருந்து எந்த நேரத்திலும் எந்த முன்னறிவிப்பும் இன்றி விலகிக்கொள்ள எனக்கு சுதந்திரம் உண்டு.

3. என்னைப்பற்றிய அடையாளங்கள், தகவல்கள் மூன்றாவது நபருக்கு தெரியப்படுத்தவோ (அ) பிரசுரிக்க படவோ மாட்டாது.

4.இந்த ஆய்வின் சோதனையின் முடிவுகள் (அ) புள்ளிவிவரங்கள் அறிவியல் உபயோகத்திற்கு மட்டுமே பயன்படுவதாக இருந்தால் கட்டுபாடு எதுவும் விதிக்காமலிருக்க உடன்படுகிறேன்.

5. இந்த ஆய்வில் பங்கேற்க சம்மதிக்கிறேன்.

தேதி: பங்கேற்பவரின் கையொப்பம்

(அ) பெருவிரல் குறி

ஆய்வாளரின் பெயர்: கையொப்பம்:

சாட்சியின் பெயர்: கையொப்பம் (அ) பெருவிரல் குறி

ANNEXURE - 9

Sno	Name	Age	Sex	Mech of injury	Type of fracture	Gustilo's class	AO class	Fibula fracture	Time to surgery (days)	Fibula fixation	Type of nail	Poller screw
1	GAN	21	M	HE	OPEN	TY 3B	A2	YES	1	NO	CONV	YES
2	SDR	20	M	HE	CLOSED		A3	YES	8	YES	ZERO	NO
3	NRS	56	M	HE	CLOSED		A2	YES	15	NO	ZERO	YES
4	AKR	19	M	HE	OPEN	TY 1	A1	YES	2	NO	ZERO	YES
5	PSA	71	F	LE	CLOSED		A2	YES	2	NO	ZERO	YES
6	GDY	77	M	HE	OPEN	TY 3B	A1	YES	7	NO	ZERO	YES
7	KPN	47	M	HE	OPEN	TY 3A	A1	YES	53	NO	ZERO	YES
8	TYL	57	F	HE	CLOSED		A1	YES	2	YES	CONV	YES
9	RSR	24	M	HE	CLOSED		A1	YES	4	YES	ZERO	NO
10	VKN	56	M	HE	CLOSED		A2	YES	1	YES	ZERO	YES
11	MHN	45	M	HE	OPEN	TY 3B	A3	YES	2	YES	ZERO	NO
12	SVL	34	M	HE	OPEN	TY 2	A1	YES	1	NO	ZERO	NO
13	RKR	48	M	HE	CLOSED		A1	NO	5	NO	CONV	NO
14	CTA	38	F	HE	CLOSED		A2	NO	2	YES	CONV	NO
15	DDL	58	M	LE	CLOSED		A2	YES	5	NO	ZERO	YES
16	MLI	41	F	HE	OPEN	TY 3B	A3	YES	1	NO	CONV	NO
17	PRN	34	M	HE	OPEN	TY 3A	A3	YES	1	YES	CONV	NO
18	LSI	33	F	LE	CLOSED		A1	NO	1	NO	ZERO	YES
19	DDN	45	M	HE	CLOSED		A2	YES	3	NO	CONV	NO
20	AMR	27	M	HE	CLOSED		A2	YES	6	NO	CONV	YES
21	JSL	69	M	HE	CLOSED		A2	YES	2	NO	ZERO	YES
22	KKN	32	M	HE	OPEN	TY 1	A1	YES	3	YES	ZERO	YES
23	PSN	57	M	HE	CLOSED		A3	YES	9	YES	ZERO	NO
24	GYR	34	F	LE	CLOSED		A2	YES	3	NO	CONV	NO
25	AUN	25	M	HE	OPEN	TY 3B	A3	NO	2	NO	CONV	YES

ANNEXURE - 9

Sno	Name	Distance (cms)	Imm postop valgus (deg)	FUP valgus 1yr(deg)	Imm postop pro/recurv (deg)	FUP pro/rec 1yr(deg)	Radiological union (wks)
1	GAN	9.0	11.2	14.8	6.0	4.0	34
2	SDR	5.9	2.4	0.3	5.2	3.2	18
3	NRS	7.6	6.7	2.1	7.5	2.2	24
4	AKR	6.6	1.3	0.2	5.7	3.9	12
5	PSA	9.6	3.6	6.8	14.4	16.5	15
6	GDY	5.6	5.7				
7	KPN	10.2	13.2	12.0	7.4	7.2	17
8	TYL	8.9	12.0	7.0	6.8	5.3	18
9	RSR	10.8	1.0	2.8	0.0	0.0	23
10	VKN	9.3	2.5	1.1	7.2	2.6	18
11	MHN	5.1	9.0	11.7	12.3	4.2	28
12	SVL	8.9	10.0	3.3	3.6	4.1	24
13	RKR	10.4	6.8	6.0	4.8	11.7	28
14	CTA	8.5	0.0	0.0	0.0	0.0	16
15	DDL	7.0	0.0	0.0	2.4	2.1	20
16	MLI	8.8	5.4	2.2	5.5	5.2	20
17	PRN	5.9	0.7	1.0	8.7	0.2	24
18	LSI	10.5	4.7	9.2	4.5	10.3	18
19	DDN	8.9	8.2	3.0	2.1	2.9	20
20	AMR	10.7	6.6	7.3	3.6	6.5	12
21	JSL	6.8	3.6	3.0	3.4	0.6	18
22	KKN	4.0	1.5	1.3	5.3	0.0	12
23	PSN	6.6	8.0	6.0	6.19(Rec)	10.4	24
24	GYR	10.5	6.8	2.4	0.4	0.4	16
25	AUN	7.8	3.3	1.2	2.9	5.6	18

ANNEXURE - 9

Sno	Name	Partial wb (wks)	Full wb (wks)	Return to work (wks)	Non-union	Malunion	Implant pain	Implant exit	AOFAS	OLMS
1	GAN	20	34	54	NO	YES	NO	NO	90	100
2	SDR	06	08	32	NO	NO	NO	NO	88	100
3	NRS	12	16	30	NO	NO	YES	NO	88	50
4	AKR	06	12	16	NO	NO	NO	NO	84	75
5	PSA	02	12	15	YES	YES	YES	YES	88	60
6	GDY									
7	KPN	20	20	NO	NO	YES	NO	NO	100	70
8	TYL	14	30	40	NO	YES	YES	YES	64	20
9	RSR	20	34	54	NO	NO	YES	NO	90	85
10	VKN	14	20	24	NO	NO	NO	NO	88	90
11	MHN	06	12	12	NO	YES	NO	NO	88	95
12	SVL	12	20	24	NO	NO	NO	NO	88	100
13	RKR	12	28	40	NO	YES	YES	YES	98	100
14	CTA	20	40	40	NO	NO	NO	NO	85	60
15	DDL	16	28	32	NO	NO	NO	NO	93	95
16	MLI	12	20	28	YES	NO	NO	NO	60	65
17	PRN	04	12	28	NO	NO	NO	NO	100	90
18	LSI	08	20	24	NO	YES	NO	NO	87	70
19	DDN	12	24	40	NO	NO	YES	YES	96	75
20	AMR	02	06	12	NO	YES	NO	NO	93	100
21	JSL	12	20	24	NO	NO	NO	NO	96	95
22	KKN	02	12	40	NO	NO	NO	NO	100	95
23	PSN	08	12	NO	NO	YES	YES	NO	73	65
24	GYR	12	16	24	NO	NO	NO	NO	93	95
25	AUN	12	16	40	NO	NO	NO	NO	90	100